

June 27 (legislative day, June 26), 2003

Ordered to be printed as passed

108TH CONGRESS
1ST SESSION

S. 1

AN ACT

To amend title XVIII of the Social Security Act to provide for a voluntary prescription drug benefit under the medicare program and to strengthen and improve the medicare program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECU-**
4 **RITY ACT; REFERENCES TO BIPA AND SEC-**
5 **RETARY; TABLE OF CONTENTS.**

6 (a) **SHORT TITLE.**—This Act may be cited as the
7 “Prescription Drug and Medicare Improvement Act of
8 2003”.

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) BIPA; SECRETARY.—In this Act:

(1) BIPA.—The term “BIPA” means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106–554.

(2) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(d) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; amendments to Social Security Act; references to BIPA and Secretary; table of contents.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Subtitle A—Medicare Voluntary Prescription Drug Delivery Program

Sec. 101. Medicare voluntary prescription drug delivery program.

“PART D—VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM

“Sec. 1860D. Definitions; treatment of references to provisions in Medicare Advantage program.

“Subpart 1—Establishment of Voluntary Prescription Drug Delivery Program

“Sec. 1860D–1. Establishment of voluntary prescription drug delivery program.

“Sec. 1860D–2. Enrollment under program.

“Sec. 1860D–3. Election of a Medicare Prescription Drug plan.

“Sec. 1860D–4. Providing information to beneficiaries.

“Sec. 1860D–5. Beneficiary protections.

“Sec. 1860D–6. Prescription drug benefits.

- “Sec. 1860D-7. Requirements for entities offering Medicare Prescription Drug plans; establishment of standards.

“Subpart 2—Prescription Drug Delivery System

- “Sec. 1860D-10. Establishment of service areas.
- “Sec. 1860D-11. Publication of risk adjusters.
- “Sec. 1860D-12. Submission of bids for proposed Medicare Prescription Drug plans.
- “Sec. 1860D-13. Approval of proposed Medicare Prescription Drug plans.
- “Sec. 1860D-14. Computation of monthly standard prescription drug coverage premiums.
- “Sec. 1860D-15. Computation of monthly national average premium.
- “Sec. 1860D-16. Payments to eligible entities.
- “Sec. 1860D-17. Computation of monthly beneficiary obligation.
- “Sec. 1860D-18. Collection of monthly beneficiary obligation.
- “Sec. 1860D-19. Premium and cost-sharing subsidies for low-income individuals.
- “Sec. 1860D-20. Reinsurance payments for expenses incurred in providing prescription drug coverage above the annual out-of-pocket threshold.
- “Sec. 1860D-21. Direct subsidy for sponsor of a qualified retiree prescription drug plan for plan enrollees eligible for, but not enrolled in, this part.
- “Sec. 1860D-22. Direct subsidies for qualified State offering a State pharmaceutical assistance program for program enrollees eligible for, but not enrolled in, this part.

“Subpart 3—Miscellaneous Provisions

- “Sec. 1860D-25. Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.
- “Sec. 1860D-26. Other related provisions.
- Sec. 102. Study and report on permitting part B only individuals to enroll in medicare voluntary prescription drug delivery program.
- Sec. 103. Rules relating to medigap policies that provide prescription drug coverage.
- Sec. 104. Medicaid and other amendments related to low-income beneficiaries.
- Sec. 105. Expansion of membership and duties of Medicare Payment Advisory Commission (MedPAC).
- Sec. 106. Study regarding variations in spending and drug utilization.
- Sec. 107. Limitation on prescription drug benefits of Members of Congress.
- Sec. 108. Protecting seniors with cancer.
- Sec. 109. Protecting seniors with cardiovascular disease, cancer, or Alzheimer’s disease.
- Sec. 110. Review and report on current standards of practice for pharmacy services provided to patients in nursing facilities.
- Sec. 110A. Medication therapy management assessment program.

Subtitle B—Medicare Prescription Drug Discount Card and Transitional Assistance for Low-Income Beneficiaries

- Sec. 111. Medicare prescription drug discount card and transitional assistance for low-income beneficiaries.

Subtitle C—Standards for Electronic Prescribing

Sec. 121. Standards for electronic prescribing.

Subtitle D—Other Provisions

- Sec. 131. Additional requirements for annual financial report and oversight on medicare program.
 Sec. 132. Trustees' report on medicare's unfunded obligations.
 Sec. 133. Pharmacy benefit managers transparency requirements.
 Sec. 134. Office of the Medicare Beneficiary Advocate.

TITLE II—MEDICAREADVANTAGE

Subtitle A—MedicareAdvantage Competition

- Sec. 201. Eligibility, election, and enrollment.
 Sec. 202. Benefits and beneficiary protections.
 Sec. 203. Payments to MedicareAdvantage organizations.
 Sec. 204. Submission of bids; premiums.
 Sec. 205. Special rules for prescription drug benefits.
 Sec. 206. Facilitating employer participation.
 Sec. 207. Administration by the Center for Medicare Choices.
 Sec. 208. Conforming amendments.
 Sec. 209. Effective date.
 Sec. 210. Improvements in MedicareAdvantage benchmark determinations.

Subtitle B—Preferred Provider Organizations

- Sec. 211. Establishment of MedicareAdvantage preferred provider program option.

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- Sec. 221. Extension of reasonable cost contracts.
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SUBTITLE D—EVALUATION OF ALTERNATIVE PAYMENT AND DELIVERY SYSTEMS

- Sec. 231. Establishment of alternative payment system for preferred provider organizations in highly competitive regions.
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SUBTITLE E—NATIONAL BIPARTISAN COMMISSION ON MEDICARE REFORM

- Sec. 241. MedicareAdvantage goal; establishment of Commission.
 Sec. 242. National bipartisan commission on medicare reform.
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TITLE III—CENTER FOR MEDICARE CHOICES

- Sec. 301. Establishment of the Center for Medicare Choices.

Sec. 302. Miscellaneous administrative provisions.

TITLE IV—MEDICARE FEE-FOR-SERVICE IMPROVEMENTS

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- Sec. 401. Equalizing urban and rural standardized payment amounts under the medicare inpatient hospital prospective payment system.
- Sec. 402. Adjustment to the medicare inpatient hospital PPS wage index to revise the labor-related share of such index.
- Sec. 403. Medicare inpatient hospital payment adjustment for low-volume hospitals.
- Sec. 404. Fairness in the medicare disproportionate share hospital (DSH) adjustment for rural hospitals.
- Sec. 404A. Medpac study and report regarding medicare Disproportionate Share Hospital (DSH) adjustment payments.
- Sec. 405. Critical access hospital (CAH) improvements.
- Sec. 406. Authorizing use of arrangements to provide core hospice services in certain circumstances.
- Sec. 407. Services provided to hospice patients by nurse practitioners, clinical nurse specialists, and physician assistants.
- Sec. 408. Authority to include costs of training of psychologists in payments to hospitals under medicare.
- Sec. 409. Revision of Federal rate for hospitals in Puerto Rico.
- Sec. 410. Exception to initial residency period for geriatric residency or fellowship programs.
- Sec. 411. Clarification of congressional intent regarding the counting of residents in a nonprovider setting and a technical amendment regarding the 3-year rolling average and the IME ratio.
- Sec. 412. Limitation on charges for inpatient hospital contract health services provided to Indians by medicare participating hospitals.
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- Sec. 414. Rural community hospital demonstration program.
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- Sec. 417. Treatment of certain entities for purposes of payments under the medicare program.
- Sec. 418. Revision of the indirect medical education (IME) adjustment percentage.
- Sec. 419. Calculation of wage indices for hospitals.
- Sec. 420. Conforming changes regarding federally qualified health centers.
- Sec. 420A. Increase for hospitals with disproportionate indigent care revenues.
- Sec. 420B. Treatment of grandfathered long-term care hospitals.

Subtitle B—Provisions Relating to Part B

- Sec. 421. Establishment of floor on geographic adjustments of payments for physicians' services.
- Sec. 422. Medicare incentive payment program improvements.
- Sec. 423. Extension of hold harmless provisions for small rural hospitals and treatment of certain sole community hospitals to limit decline in payment under the OPD PPS.
- Sec. 424. Increase in payments for certain services furnished by small rural and sole community hospitals under medicare prospective payment system for hospital outpatient department services.

- Sec. 425. Temporary increase for ground ambulance services.
- Sec. 426. Ensuring appropriate coverage of air ambulance services under ambulance fee schedule.
- Sec. 427. Treatment of certain clinical diagnostic laboratory tests furnished by a sole community hospital.
- Sec. 428. Improvement in rural health clinic reimbursement.
- Sec. 429. Elimination of consolidated billing for certain services under the medicare PPS for skilled nursing facility services.
- Sec. 430. Freeze in payments for certain items of durable medical equipment and certain orthotics; establishment of quality standards and accreditation requirements for DME providers.
- Sec. 431. Application of coinsurance and deductible for clinical diagnostic laboratory tests.
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- Sec. 439. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
- Sec. 440. Demonstration of coverage of chiropractic services under medicare.
- Sec. 441. Medicare health care quality demonstration programs.
- Sec. 442. Medicare complex clinical care management payment demonstration.
- Sec. 443. Medicare fee-for-service care coordination demonstration program.
- Sec. 444. GAO study of geographic differences in payments for physicians' services.
- Sec. 445. Improved payment for certain mammography services.
- Sec. 446. Improvement of outpatient vision services under Part B.
- Sec. 447. GAO study and report on the propagation of concierge care.
- Sec. 448. Coverage of marriage and family therapist services and mental health counselor services under Part B of the medicare program.
- Sec. 449. Medicare demonstration project for direct access to physical therapy services.
- Sec. 450. Demonstration project to clarify the definition of homebound.
- Sec. 450A. Demonstration project for exclusion of brachytherapy devices from prospective payment system for outpatient hospital services.
- Sec. 450B. Reimbursement for total body orthotic management for certain nursing home patients.
- Sec. 450C. Authorization of reimbursement for all medicare part B services furnished by certain Indian hospitals and clinics.
- Sec. 450D. Coverage of cardiovascular screening tests.
- Sec. 450E. Medicare coverage of self-injected biologicals.
- Sec. 450F. Extension of medicare secondary payer rules for individuals with end-stage renal disease.
- Sec. 450G. Requiring the Internal Revenue Service to deposit installment agreement and other fees in the Treasury as miscellaneous receipts.
- Sec. 450H. Increasing types of originating telehealth sites and facilitating the provision of telehealth services across State lines.

- Sec. 450I. Demonstration project for coverage of surgical first assisting services of certified registered nurse first assistants.
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Subtitle C—Provisions Relating to Parts A and B

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- Sec. 455. MEDPAC study on medicare payments and efficiencies in the health care system.
- Sec. 456. Medicare coverage of kidney disease education services.
- Sec. 457. Frontier extended stay clinic demonstration project.
- Sec. 458. Improvements in national coverage determination process to respond to changes in technology.
- Sec. 459. Increase in medicare payment for certain home health services.
- Sec. 460. Frontier extended stay clinic demonstration project.
- Sec. 461. Medicare secondary payor (MSP) provisions.
- Sec. 462. Medicare pancreatic islet cell transplant demonstration project.
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- Sec. 464. Sense of the Senate concerning medicare payment update for physicians and other health professionals.

TITLE V—MEDICARE APPEALS, REGULATORY, AND CONTRACTING IMPROVEMENTS

Subtitle A—Regulatory Reform

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- Sec. 502. Compliance with changes in regulations and policies.
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Subtitle B—Appeals Process Reform

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- Sec. 601. Increase in medicaid DSH allotments for fiscal years 2004 and 2005.
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 Sec. 610. Federal reimbursement of emergency health services furnished to undocumented aliens.
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 Sec. 612. Increase in civil penalties under the False Claims Act.
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- Sec. 614. Extension of customs user fees.
- Sec. 615. Reimbursement for federally qualified health centers participating in medicare managed care.
- Sec. 616. Provision of information on advance directives.
- Sec. 617. Sense of the Senate regarding implementation of the Prescription Drug and Medicare Improvement Act of 2003.
- Sec. 618. Extension of municipal health service demonstration projects.
- Sec. 619. Study on making prescription pharmaceutical information accessible for blind and visually-impaired individuals.
- Sec. 620. Health care that works for all americans-citizens health care working group.
- Sec. 621. GAO study of pharmaceutical price controls and patent protections in the G-7 countries.
- Sec. 622. Sense of the Senate concerning medicare payment update for physicians and other health professionals.
- Sec. 623. Restoration of Federal Hospital Insurance Trust Fund.
- Sec. 624. Safety net organizations and Patient Advisory Commission.
- Sec. 625. Urban health provider adjustment.
- Sec. 626. Committee on drug compounding.
- Sec. 627. Sense of the Senate concerning the structure of medicare reform and the prescription drug benefit.
- Sec. 628. Sense of the Senate regarding the establishment of a nationwide permanent lifestyle modification program for medicare beneficiaries.
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- Sec. 630. Temporary suspension of oasis requirement for collection of data on non-medicare and non-medicaid patients.
- Sec. 631. Employer flexibility.
- Sec. 632. One Hundred percent FMAP for medical assistance provided to a Native Hawaiian through a federally-qualified health center or a Native Hawaiian health care system under the medicaid program.
- Sec. 633. Extension of moratorium.
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- Sec. 635. Safety Net Organizations and Patient Advisory Commission.
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TITLE VII—ACCESS TO AFFORDABLE PHARMACEUTICALS

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- Sec. 702. 30-month stay-of-effectiveness period.
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TITLE VIII—IMPORTATION OF PRESCRIPTION DRUGS

- Sec. 801. Importation of prescription drugs.

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- Sec. 901. Short title.
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- Sec. 903. Purposes.
- Sec. 904. Definitions.
- Sec. 905. Notification of agreements.
- Sec. 906. Filing deadlines.
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- Sec. 908. Enforcement.
- Sec. 909. Rulemaking.
- Sec. 910. Savings clause.
- Sec. 911. Effective date.

1 **TITLE I—MEDICARE**
 2 **PRESCRIPTION DRUG BENEFIT**
 3 **Subtitle A—Medicare Voluntary**
 4 **Prescription Drug Delivery Pro-**
 5 **gram**

6 **SEC. 101. MEDICARE VOLUNTARY PRESCRIPTION DRUG DE-**
 7 **LIVERY PROGRAM.**

8 (a) ESTABLISHMENT.—Title XVIII (42 U.S.C. 1395
 9 et seq.) is amended by redesignating part D as part E
 10 and by inserting after part C the following new part:

11 “PART D—VOLUNTARY PRESCRIPTION DRUG DELIVERY
 12 PROGRAM

13 “DEFINITIONS; TREATMENT OF REFERENCES TO
 14 PROVISIONS IN MEDICAREADVANTAGE PROGRAM

15 “SEC. 1860D. (a) DEFINITIONS.—In this part:

16 “(1) ADMINISTRATOR.—The term ‘Adminis-
 17 trator’ means the Administrator of the Center for
 18 Medicare Choices as established under section 1808.

19 “(2) COVERED DRUG.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraphs (B), (C), and (D), the term ‘cov-
3 ered drug’ means—

4 “(i) a drug that may be dispensed
5 only upon a prescription and that is de-
6 scribed in clause (i) or (ii) of subparagraph
7 (A) of section 1927(k)(2); or

8 “(ii) a biological product described in
9 clauses (i) through (iii) of subparagraph
10 (B) of such section; or

11 “(iii) insulin described in subpara-
12 graph (C) of such section (including sy-
13 ringes, and necessary medical supplies as-
14 sociated with the administration of insulin,
15 as defined by the Administrator);

16 and such term includes a vaccine licensed under
17 section 351 of the Public Health Service Act
18 and any use of a covered drug for a medically
19 accepted indication (as defined in section
20 1927(k)(6)).

21 “(B) EXCLUSIONS.—

22 “(i) IN GENERAL.—The term ‘covered
23 drug’ does not include drugs or classes of
24 drugs, or their medical uses, which may be
25 excluded from coverage or otherwise re-

1 stricted under section 1927(d)(2), other
2 than subparagraph (E) thereof (relating to
3 smoking cessation agents), or under sec-
4 tion 1927(d)(3).

5 “(ii) AVOIDANCE OF DUPLICATE COV-
6 ERAGE.—A drug prescribed for an indi-
7 vidual that would otherwise be a covered
8 drug under this part shall not be so con-
9 sidered if payment for such drug is avail-
10 able under part A or B, but shall be so
11 considered if such payment is not available
12 under part A or B or because benefits
13 under such parts have been exhausted. [E]

14 “(C) APPLICATION OF FORMULARY RE-
15 STRICTIONS.—A drug prescribed for an indi-
16 vidual that would otherwise be a covered drug
17 under this part shall not be so considered under
18 a plan if the plan excludes the drug under a
19 formulary and such exclusion is not successfully
20 resolved under subsection (d) or (e)(2) of sec-
21 tion 1860D-5.

22 “(D) APPLICATION OF GENERAL EXCLU-
23 SION PROVISIONS.—A Medicare Prescription
24 Drug plan or a Medicare Advantage plan may

exclude from qualified prescription drug coverage any covered drug—

“(i) for which payment would not be made if section 1862(a) applied to part D;

to survivor beneficiaries (E).”

“(ii) which are not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to section 1860D-5(e).

“(3) ELIGIBLE BENEFICIARY.—The term ‘eligible beneficiary’ means an individual who is entitled to, or enrolled for, benefits under part A and enrolled under part B (other than a dual eligible individual, as defined in section 1860D-19(a)(4)(E)).

“(4) ELIGIBLE ENTITY.—The term ‘eligible entity’ means any risk-bearing entity that the Administrator determines to be appropriate to provide eligible beneficiaries with the benefits under a Medicare Prescription Drug plan, including—

“(A) a pharmaceutical benefit management company;

“(B) a wholesale or retail pharmacist delivery system;

1 “(C) an insurer (including an insurer that
2 offers medicare supplemental policies under sec-
3 tion 1882);

4 “(D) any other risk-bearing entity; or

5 “(E) any combination of the entities de-
6 scribed in subparagraphs (A) through (D).

7 “(5) INITIAL COVERAGE LIMIT.—The term ‘ini-
8 tial coverage limit’ means the limit as established
9 under section 1860D–6(c)(3), or, in the case of cov-
10 erage that is not standard prescription drug cov-
11 erage, the comparable limit (if any) established
12 under the coverage.

13 “(6) MEDICAREADVANTAGE ORGANIZATION;
14 MEDICAREADVANTAGE PLAN.—The terms
15 ‘MedicareAdvantage organization’ and
16 ‘MedicareAdvantage plan’ have the meanings given
17 such terms in subsections (a)(1) and (b)(1), respec-
18 tively, of section 1859 (relating to definitions relat-
19 ing to MedicareAdvantage organizations).

20 “(7) MEDICARE PRESCRIPTION DRUG PLAN.—
21 The term ‘Medicare Prescription Drug plan’ means
22 prescription drug coverage that is offered under a
23 policy, contract, or plan—

24 “(A) that has been approved under section
25 1860D–13; and

“(B) by an eligible entity pursuant to, and in accordance with, a contract between the Administrator and the entity under section 1860D-7(b).

“(8) PRESCRIPTION DRUG ACCOUNT.—The term ‘Prescription Drug Account’ means the Prescription Drug Account (as established under section 1860D-25) in the Federal Supplementary Medical Insurance Trust Fund under section 1841.

“(9) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term ‘qualified prescription drug coverage’ means the coverage described in section 1860D-6(a)(1).

“(10) STANDARD PRESCRIPTION DRUG COVERAGE.—The term ‘standard prescription drug coverage’ means the coverage described in section 1860D-6(c).

“(b) APPLICATION OF MEDICAREADVANTAGE PROVISIONS UNDER THIS PART.—For purposes of applying provisions of part C under this part with respect to a Medicare Prescription Drug plan and an eligible entity, unless otherwise provided in this part such provisions shall be applied as if—

1 “(1) any reference to a MedicareAdvantage
2 plan included a reference to a Medicare Prescription
3 Drug plan;

4 “(2) any reference to a provider-sponsored or-
5 ganization included a reference to an eligible entity;

6 “(3) any reference to a contract under section
7 1857 included a reference to a contract under sec-
8 tion 1860D-7(b); and

9 “(4) any reference to part C included a ref-
10 erence to this part.

11 “Subpart 1—Establishment of Voluntary Prescription

12 Drug Delivery Program

13 “ESTABLISHMENT OF VOLUNTARY PRESCRIPTION DRUG
14 DELIVERY PROGRAM

15 “SEC. 1860D-1. (a) PROVISION OF BENEFIT.—

16 “(1) IN GENERAL.—The Administrator shall
17 provide for and administer a voluntary prescription
18 drug delivery program under which each eligible ben-
19 eficiary enrolled under this part shall be provided
20 with access to qualified prescription drug coverage
21 as follows:

22 “(A) MEDICAREADVANTAGE ENROLLEES
23 RECEIVE COVERAGE THROUGH
24 MEDICAREADVANTAGE PLAN.—

1 “(i) IN GENERAL.—Except as pro-
 2 ~~in clause (i)~~ vided in clause (ii), an eligible beneficiary
 3 ~~may~~ who is enrolled under this part and en-
 4 rolled in a MedicareAdvantage plan offered
 5 by a MedicareAdvantage organization shall
 6 receive coverage of benefits under this part
 7 through such plan.

8 ~~in clause (ii)~~“(ii) EXCEPTION FOR ENROLLEES IN
 9 MEDICAREADVANTAGE MSA PLANS.—An el-
 10 igible beneficiary who is enrolled under this
 11 part and enrolled in an MSA plan under
 12 part C shall receive coverage of benefits
 13 under this part through enrollment in a
 14 Medicare Prescription Drug plan that is
 15 offered in the geographic area in which the
 16 beneficiary resides. For purposes of this
 17 part, the term ‘MSA plan’ has the meaning
 18 given such term in section 1859(b)(3).

19 ~~part of paragraph (ii)~~“(iii) EXCEPTION FOR ENROLLEES IN
 20 MEDICAREADVANTAGE PRIVATE FEE-FOR-
 21 SERVICE PLANS.—An eligible beneficiary
 22 who is enrolled under this part and en-
 23 rolled in a private fee-for-service plan
 24 under part C shall—

1 “(i) receive benefits under this
 2 part through such plan if the plan
 3 provides qualified prescription drug
 4 coverage; and

5 “(ii) if the plan does not provide
 6 qualified prescription drug coverage,
 7 receive coverage of benefits under this
 8 part through enrollment in a Medicare
 9 Prescription Drug plan that is offered
 10 in the geographic area in which the
 11 beneficiary resides. For purposes of
 12 this part, the term ‘private fee-for-
 13 service plan’ has the meaning given
 14 such term in section 1859(b)(2).

15 “(B) FEE-FOR-SERVICE ENROLLEES RE-
 16 CEIVE COVERAGE THROUGH A MEDICARE PRE-
 17 SCRIPTION DRUG PLAN.—An eligible beneficiary
 18 who is enrolled under this part but is not en-
 19 rolled in a Medicare Advantage plan (except for
 20 an MSA plan or a private fee-for-service plan
 21 that does not provide qualified prescription
 22 drug coverage) shall receive coverage of benefits
 23 under this part through enrollment in a Medi-
 24 care Prescription Drug plan that is offered in

the geographic area in which the beneficiary resides.

“(2) VOLUNTARY NATURE OF PROGRAM.—

Nothing in this part shall be construed as requiring an eligible beneficiary to enroll in the program under this part.

“(3) SCOPE OF BENEFITS.—Pursuant to section 1860D-6(b)(3)(C), the program established under this part shall provide for coverage of all therapeutic categories and classes of covered drugs (although not necessarily for all drugs within such categories and classes).

“(4) PROGRAM TO BEGIN IN 2006.—The Administrator shall establish the program under this part in a manner so that benefits are first provided beginning on January 1, 2006.

“(b) ACCESS TO ALTERNATIVE PRESCRIPTION DRUG COVERAGE.—In the case of an eligible beneficiary who has creditable prescription drug coverage (as defined in section 1860D-2(b)(1)(F)), such beneficiary—

“(1) may continue to receive such coverage and not enroll under this part; and

“(2) pursuant to section 1860D-2(b)(1)(C), is permitted to subsequently enroll under this part without any penalty and obtain access to qualified

1 prescription drug coverage in the manner described
 2 in subsection (a) if the beneficiary involuntarily loses
 3 such coverage.

4 “(c) FINANCING.—The costs of providing benefits
 5 under this part shall be payable from the Prescription
 6 Drug Account.

7 “ENROLLMENT UNDER PROGRAM

8 “SEC. 1860D-2. (a) ESTABLISHMENT OF ENROLL-
 9 MENT PROCESS.—

10 “(1) PROCESS SIMILAR TO PART B ENROLL-
 11 MENT.—The Administrator shall establish a process
 12 through which an eligible beneficiary (including an
 13 eligible beneficiary enrolled in a MedicareAdvantage
 14 plan offered by a MedicareAdvantage organization)
 15 may make an election to enroll under this part. Such
 16 process shall be similar to the process for enrollment
 17 in part B under section 1837, including the deeming
 18 provisions of such section.

19 “(2) CONDITION OF ENROLLMENT.—An eligible
 20 beneficiary must be enrolled under this part in order
 21 to be eligible to receive access to qualified prescrip-
 22 tion drug coverage.

23 “(b) SPECIAL ENROLLMENT PROCEDURES.—

24 “(1) LATE ENROLLMENT PENALTY.—

25 “(A) INCREASE IN MONTHLY BENEFICIARY
 26 OBLIGATION.—Subject to the succeeding provi-

sions of this paragraph, in the case of an eligible beneficiary whose coverage period under this part began pursuant to an enrollment after the beneficiary's initial enrollment period under part B (determined pursuant to section 1837(d)) and not pursuant to the open enrollment period described in paragraph (2), the Administrator shall establish procedures for increasing the amount of the monthly beneficiary obligation under section 1860D-17 applicable to such beneficiary by an amount that the Administrator determines is actuarially sound for each full 12-month period (in the same continuous period of eligibility) in which the eligible beneficiary could have been enrolled under this part but was not so enrolled.

“(B) PERIODS TAKEN INTO ACCOUNT.—
For purposes of calculating any 12-month period under subparagraph (A), there shall be taken into account—

“(i) the months which elapsed between the close of the eligible beneficiary's initial enrollment period and the close of the enrollment period in which the beneficiary enrolled; and

1 “(ii) in the case of an eligible bene-
 2 ficiary who reenrolls under this part, the
 3 months which elapsed between the date of
 4 termination of a previous coverage period
 5 and the close of the enrollment period in
 6 which the beneficiary reenrolled.

7 “(C) PERIODS NOT TAKEN INTO AC-
 8 COUNT.—

9 “(i) IN GENERAL.—For purposes of
 10 calculating any 12-month period under
 11 subparagraph (A), subject to clause (ii),
 12 there shall not be taken into account
 13 months for which the eligible beneficiary
 14 can demonstrate that the beneficiary had
 15 creditable prescription drug coverage (as
 16 defined in subparagraph (F)).

17 “(ii) BENEFICIARY MUST INVOLUN-
 18 TARILY LOSE COVERAGE.—Clause (i) shall
 19 only apply with respect to coverage—

20 “(I) in the case of coverage de-
 21 scribed in clause (ii) of subparagraph
 22 (F), if the plan terminates, ceases to
 23 provide, or reduces the value of the
 24 prescription drug coverage under such
 25 plan to below the actuarial value of

1 a third standard prescription drug coverage
2 prescribed (as determined under section 1860D-
3 8881 under 6(f));

4 “(II) in the case of coverage de-
5 scribed in clause (i), (iii), or (iv) of
6 subparagraph (F), if the beneficiary is
7 to be involuntarily disenrolled or becomes
8 ineligible for such coverage; or

9 “(III) in the case of a beneficiary
10 with coverage described in clause (v)
11 of subparagraph (F), if the issuer of
12 the policy terminates coverage under
13 the policy.

14 “(D) PERIODS TREATED SEPARATELY.—
15 Any increase in an eligible beneficiary’s monthly
16 beneficiary obligation under subparagraph (A)
17 with respect to a particular continuous period
18 of eligibility shall not be applicable with respect
19 to any other continuous period of eligibility
20 which the beneficiary may have.

21 “(E) CONTINUOUS PERIOD OF ELIGI-
22 BILITY.—

23 “(i) IN GENERAL.—Subject to clause
24 (ii), for purposes of this paragraph, an eli-
25 gible beneficiary’s ‘continuous period of eli-

gibility' is the period that begins with the first day on which the beneficiary is eligible to enroll under section 1836 and ends with the beneficiary's death.

“(ii) SEPARATE PERIOD.—Any period during all of which an eligible beneficiary satisfied paragraph (1) of section 1836 and which terminated in or before the month preceding the month in which the beneficiary attained age 65 shall be a separate ‘continuous period of eligibility’ with respect to the beneficiary (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this paragraph).

“(F) CREDITABLE PRESCRIPTION DRUG COVERAGE DEFINED.—Subject to subparagraph (G), for purposes of this part, the term ‘creditable prescription drug coverage’ means any of the following:

“(i) DRUG-ONLY COVERAGE UNDER MEDICAID.—Coverage of covered outpatient drugs (as defined in section 1927) under title XIX or a waiver under 1115 that is provided to an individual who is not

a dual eligible individual (as defined in section 1860D-19(a)(4)(E)).

“(ii) PRESCRIPTION DRUG COVERAGE UNDER A GROUP HEALTH PLAN.—Any outpatient prescription drug coverage under a group health plan, including a health benefits plan under chapter 89 of title 5, United States Code (commonly known as the Federal employees health benefits program), and a qualified retiree prescription drug plan (as defined in section 1860D-20(e)(4)).

“(iii) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program.

“(iv) VETERANS’ COVERAGE OF PRESCRIPTION DRUGS.—Coverage of prescription drugs for veterans, and survivors and dependents of veterans, under chapter 17 of title 38, United States Code.

“(v) PRESCRIPTION DRUG COVERAGE UNDER MEDIGAP POLICIES.—Coverage under a medicare supplemental policy under section 1882 that provides benefits

1 for prescription drugs (whether or not such
 2 coverage conforms to the standards for
 3 packages of benefits under section
 4 1882(p)(1)).

5 “(G) REQUIREMENT FOR CREDITABLE
 6 COVERAGE.—Coverage described in clauses (i)
 7 through (v) of subparagraph (F) shall not be
 8 considered to be creditable coverage under this
 9 part unless the coverage provides coverage of
 10 the cost of prescription drugs the actuarial
 11 value of which (as defined by the Adminis-
 12 trator) to the beneficiary equals or exceeds the
 13 actuarial value of standard prescription drug
 14 coverage (as determined under section 1860D-
 15 6(f)).

16 “(H) DISCLOSURE.—

17 “(i) IN GENERAL.—Each entity that
 18 offers coverage of the type described in
 19 clause (ii) (iii), (iv), or (v) of subparagraph
 20 (F) shall provide for disclosure, consistent
 21 with standards established by the Adminis-
 22 trator, of whether the coverage provides
 23 coverage of the cost of prescription drugs
 24 the actuarial value of which (as defined by
 25 the Administrator) to the beneficiary

1 equals or exceeds the actuarial value of
 2 standard prescription drug coverage (as
 3 determined under section 1860D-6(f)).

4 ~~It is hereby~~“(ii) WAIVER OF LIMITATIONS.—An
 5 individual may apply to the Administrator
 6 to waive the application of subparagraph
 7 (G) if the individual establishes that the
 8 individual was not adequately informed
 9 that the coverage the beneficiary was en-
 10 rolled in did not provide the level of bene-
 11 fits required in order for the coverage to be
 12 considered creditable coverage under sub-
 13 paragraph (F). ~~provided no other~~

14 “(2) INITIAL ELECTION PERIODS.—

15 “(A) OPEN ENROLLMENT PERIOD FOR
 16 CURRENT BENEFICIARIES IN WHICH LATE EN-
 17 ROLLMENT PROCEDURES DO NOT APPLY.—In
 18 the case of an individual who is an eligible ben-
 19 eficiary as of November 1, 2005, there shall be
 20 an open enrollment period of 6 months begin-
 21 ning on that date under which such beneficiary
 22 may enroll under this part without the applica-
 23 tion of the late enrollment procedures estab-
 24 lished under paragraph (1)(A).

1 “(B) INDIVIDUAL COVERED IN FUTURE.—

2 In the case of an individual who becomes an eli-
3 gible beneficiary after such date, there shall be
4 an initial election period which is the same as
5 the initial enrollment period under section
6 1837(d).

7 “(3) SPECIAL ENROLLMENT PERIOD FOR BENE-
8 FICIARIES WHO INVOLUNTARILY LOSE CREDITABLE
9 PRESCRIPTION DRUG COVERAGE.—

10 “(A) ESTABLISHMENT.—The Adminis-
11 trator shall establish a special open enrollment
12 period (as described in subparagraph (B)) for
13 an eligible beneficiary that loses creditable pre-
14 scription drug coverage.

15 “(B) SPECIAL OPEN ENROLLMENT PE-
16 RIOD.—The special open enrollment period de-
17 scribed in this subparagraph is the 63-day pe-
18 riod that begins on—

19 “(i) in the case of a beneficiary with
20 coverage described in clause (ii) of para-
21 graph (1)(F), the later of the date on
22 which the plan terminates, ceases to pro-
23 vide, or substantially reduces (as defined
24 by the Administrator) the value of the pre-
25 scription drug coverage under such plan or

the date the beneficiary is provided with
notice of such termination or reduction;

“(ii) in the case of a beneficiary with
coverage described in clause (i), (iii), or
(iv) of paragraph (1)(F), the later of the
date on which the beneficiary is involun-
tarily disenrolled or becomes ineligible for
such coverage or the date the beneficiary is
provided with notice of such loss of eligi-
bility; or

“(iii) in the case of a beneficiary with
coverage described in clause (v) of para-
graph (1)(F), the latter of the date on
which the issuer of the policy terminates
coverage under the policy or the date the
beneficiary is provided with notice of such
termination.

“(c) PERIOD OF COVERAGE.—

“(1) IN GENERAL.—Except as provided in para-
graph (2) and subject to paragraph (3), an eligible
beneficiary’s coverage under the program under this
part shall be effective for the period provided in sec-
tion 1838, as if that section applied to the program
under this part.

“(2) OPEN AND SPECIAL ENROLLMENT.—

1 “(A) OPEN ENROLLMENT.—An eligible
2 beneficiary who enrolls under the program
3 under this part pursuant to subsection (b)(2)
4 shall be entitled to the benefits under this part
5 beginning on January 1, 2006.

6 “(B) SPECIAL ENROLLMENT.—Subject to
7 paragraph (3), an eligible beneficiary who en-
8 rolls under the program under this part pursu-
9 ant to subsection (b)(3) shall be entitled to the
10 benefits under this part beginning on the first
11 day of the month following the month in which
12 such enrollment occurs.

13 “(3) LIMITATION.—Coverage under this part
14 shall not begin prior to January 1, 2006.

15 “(d) TERMINATION.—

16 “(1) IN GENERAL.—The causes of termination
17 specified in section 1838 shall apply to this part in
18 the same manner as such causes apply to part B.

19 “(2) COVERAGE TERMINATED BY TERMINATION
20 OF COVERAGE UNDER PART A OR B.—

21 “(A) IN GENERAL.—In addition to the
22 causes of termination specified in paragraph
23 (1), the Administrator shall terminate an indi-
24 vidual’s coverage under this part if the indi-

vidual is no longer enrolled in both parts A and
B.

“(B) EFFECTIVE DATE.—The termination
described in subparagraph (A) shall be effective
on the effective date of termination of coverage
under part A or (if earlier) under part B.

“(3) PROCEDURES REGARDING TERMINATION
OF A BENEFICIARY UNDER A PLAN.—The Adminis-
trator shall establish procedures for determining the
status of an eligible beneficiary’s enrollment under
this part if the beneficiary’s enrollment in a Medi-
care Prescription Drug plan offered by an eligible
entity under this part is terminated by the entity for
cause (pursuant to procedures established by the
Administrator under section 1860D–3(a)(1)).

“ELECTION OF A MEDICARE PRESCRIPTION DRUG PLAN

“SEC. 1860D–3. (a) IN GENERAL.—

“(1) PROCESS.—

“(A) ELECTION.—

“(i) IN GENERAL.—The Administrator
shall establish a process through which an
eligible beneficiary who is enrolled under
this part but not enrolled in a
Medicare Advantage plan (except for an
MSA plan or a private fee-for-service plan
that does not provide qualified prescription

1 drug coverage) offered by a
 2 MedicareAdvantage organization—

3 “(I) shall make an election to en-
 4 roll in any Medicare Prescription
 5 Drug plan that is offered by an eligi-
 6 ble entity and that serves the geo-
 7 graphic area in which the beneficiary
 8 resides; and

9 “(II) may make an annual elec-
 10 tion to change the election under this
 11 clause.

12 “(ii) CLARIFICATION REGARDING EN-
 13 ROLLMENT.—The process established
 14 under clause (i) shall include, in the case
 15 of an eligible beneficiary who is enrolled
 16 under this part but who has failed to make
 17 an election of a Medicare Prescription
 18 Drug plan in an area, for the enrollment
 19 in any Medicare Prescription Drug plan
 20 that has been designated by the Adminis-
 21 trator in the area. The Administrator shall
 22 establish a process for designating a plan
 23 or plans in order to carry out the pre-
 24 ceding sentence.

1 “(B) REQUIREMENTS FOR PROCESS.—In
 2 establishing the process under subparagraph
 3 (A), the Administrator shall—

4 “(i) use rules similar to the rules for
 5 enrollment, disenrollment, and termination
 6 of enrollment with a MedicareAdvantage
 7 plan under section 1851, including—

8 ~~from section 1851(g)(1)(B)(i)~~ “(I) the establishment of special
 9 ~~enrollment~~ election periods under subsection
 10 (e)(4) of such section; and

11 ~~(1851(g)(1)(B)(i)(II))~~ “(II) the application of the guar-
 12 anteed issue and renewal provisions of
 13 section 1851(g) (other than clause (i)
 14 ~~and~~ and the second sentence of clause (ii)
 15 of paragraph (3)(C), relating to de-
 16 fault enrollment); and

17 ~~[(1851(g)(1)(B)(i)(II))]~~ “(ii) coordinate enrollments,
 18 disenrollments, and terminations of enroll-
 19 ment under part C with enrollments,
 20 disenrollments, and terminations of enroll-
 21 ment under this part. ~~from~~

22 “(2) FIRST ENROLLMENT PERIOD FOR PLAN
 23 ENROLLMENT.—The process developed under para-
 24 graph (1) shall ensure that eligible beneficiaries who
 25 enroll under this part during the open enrollment

1 period under section 1860D-2(b)(2) are permitted
 2 to elect an eligible entity prior to January 1, 2006,
 3 in order to ensure that coverage under this part is
 4 effective as of such date.

5 “(b) ENROLLMENT IN A MEDICAREADVANTAGE
 6 PLAN.—

7 “(1) IN GENERAL.—An eligible beneficiary who
 8 is enrolled under this part and enrolled in a
 9 MedicareAdvantage plan (except for an MSA plan or
 10 a private fee-for-service plan that does not provide
 11 qualified prescription drug coverage) offered by a
 12 MedicareAdvantage organization shall receive access
 13 to such coverage under this part through such plan.

14 “(2) RULES.—Enrollment in a
 15 MedicareAdvantage plan is subject to the rules for
 16 enrollment in such plan under section 1851.

17 “(c) INFORMATION TO ENTITIES TO FACILITATE EN-
 18 ROLLMENT.—Notwithstanding any other provision of law,
 19 the Administrator may provide to each eligible entity with
 20 a contract under this part such information about eligible
 21 beneficiaries as the Administrator determines to be nec-
 22 essary to facilitate efficient enrollment by such bene-
 23 ficiaries with such entities. The Administrator may pro-
 24 vide such information only so long as and to the extent
 25 necessary to carry out such objective.

1 “PROVIDING INFORMATION TO BENEFICIARIES

2 “SEC. 1860D-4. (a) ACTIVITIES.—

3 “(1) IN GENERAL.—The Administrator shall
4 conduct activities that are designed to broadly dis-
5 seminate information to eligible beneficiaries (and
6 prospective eligible beneficiaries) regarding the cov-
7 erage provided under this part.

8 “(2) SPECIAL RULE FOR FIRST ENROLLMENT
9 UNDER THE PROGRAM.—The activities described in
10 paragraph (1) shall ensure that eligible beneficiaries
11 are provided with such information at least 30 days
12 prior to the first enrollment period described in sec-
13 tion 1860D-3(a)(2).

14 “(b) REQUIREMENTS.—

15 “(1) IN GENERAL.—The activities described in
16 subsection (a) shall—

17 “(A) be similar to the activities performed
18 by the Administrator under section 1851(d);

19 “(B) be coordinated with the activities per-
20 formed by—

21 “(i) the Administrator under such sec-
22 tion; and

23 “(ii) the Secretary under section
24 1804; and

1 “(C) provide for the dissemination of infor-
2 mation comparing the plans offered by eligible
3 entities under this part that are available to eli-
4 gible beneficiaries residing in an area.

5 “(2) COMPARATIVE INFORMATION.—The com-
6 parative information described in paragraph (1)(C)
7 shall include a comparison of the following:

8 “(A) BENEFITS.—The benefits provided
9 under the plan and the formularies and griev-
10 ance and appeals processes under the plan.

11 “(B) MONTHLY BENEFICIARY OBLIGA-
12 TION.—The monthly beneficiary obligation
13 under the plan.

14 “(C) QUALITY AND PERFORMANCE.—The
15 quality and performance of the eligible entity
16 offering the plan.

17 “(D) BENEFICIARY COST-SHARING.—The
18 cost-sharing required of eligible beneficiaries
19 under the plan.

20 “(E) CONSUMER SATISFACTION SUR-
21 VEYS.—The results of consumer satisfaction
22 surveys regarding the plan and the eligible enti-
23 ty offering such plan (conducted pursuant to
24 section 1860D-5(h).

“(F) ADDITIONAL INFORMATION.—Such additional information as the Administrator may prescribe.

“BENEFICIARY PROTECTIONS

“SEC. 1860D–5. (a) DISSEMINATION OF INFORMATION.—

“(1) GENERAL INFORMATION.—An eligible entity offering a Medicare Prescription Drug plan shall disclose, in a clear, accurate, and standardized form to each enrollee at the time of enrollment, and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan. Such information includes the following:

“(A) Access to covered drugs, including access through pharmacy networks.

“(B) How any formulary used by the entity functions.

“(C) Copayments, coinsurance, and deductible requirements.

“(D) Grievance and appeals processes.

The information described in the preceding sentence shall also be made available on request to prospective enrollees during open enrollment periods.

“(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of an individual eligible to en-

roll in a Medicare Prescription Drug plan, the eligible entity offering such plan shall provide information similar (as determined by the Administrator) to the information described in subparagraphs (A), (B), and (C) of section 1852(c)(2) to such individual.

“(3) RESPONSE TO BENEFICIARY QUESTIONS.—

An eligible entity offering a Medicare Prescription Drug plan shall have a mechanism for providing on a timely basis specific information to enrollees upon request, including information on the coverage of specific drugs and changes in its formulary.

“(4) CLAIMS INFORMATION.—An eligible entity offering a Medicare Prescription Drug plan must furnish to enrolled individuals in a form easily understandable to such individuals—

“(A) an explanation of benefits (in accordance with section 1806(a) or in a comparable manner); and

“(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to the initial coverage limit and annual out-of-pocket limit for the current year (except that such notice need not be provided more often than monthly).

1 “(5) APPROVAL OF MARKETING MATERIAL AND
2 APPLICATION FORMS.—The provisions of section
3 1851(h) shall apply to marketing material and appli-
4 cation forms under this part in the same manner as
5 such provisions apply to marketing material and ap-
6 plication forms under part C.

7 “(b) ACCESS TO COVERED DRUGS.—

8 “(1) ACCESS TO NEGOTIATED PRICES FOR PRE-
9 SCRIPTION DRUGS.—An eligible entity offering a
10 Medicare Prescription Drug plan shall have in place
11 procedures to ensure that beneficiaries are not
12 charged more than the negotiated price of a covered
13 drug. Such procedures shall include the issuance of
14 a card (or other technology) that may be used by an
15 enrolled beneficiary for the purchase of prescription
16 drugs for which coverage is not otherwise provided
17 under the Medicare Prescription Drug plan.

18 “(2) ASSURING PHARMACY ACCESS.—

19 “(A) IN GENERAL.—An eligible entity of-
20 fering a Medicare Prescription Drug plan shall
21 secure the participation in its network of a suf-
22 ficient number of pharmacies that dispense
23 (other than by mail order) drugs directly to pa-
24 tients to ensure convenient access (as deter-
25 mined by the Administrator and including ade-

quate emergency access) for enrolled beneficiaries, in accordance with standards established by the Administrator under section 1860D-7(g) that ensure such convenient access. Such standards shall take into account reasonable distances to pharmacy services in urban and rural areas and access to pharmacy services of the Indian Health Service and Indian tribes and tribal organizations.

“(B) USE OF POINT-OF-SERVICE SYSTEM.—An eligible entity offering a Medicare Prescription Drug plan shall establish an optional point-of-service method of operation under which—

“(i) the plan provides access to any or all pharmacies that are not participating pharmacies in its network; and

“(ii) the plan may charge beneficiaries through adjustments in copayments any additional costs associated with the point-of-service option.

The additional copayments so charged shall not count toward the application of section 1860D-6(c).

“(C) LEVEL PLAYING FIELD.—An eligible entity offering a Medicare Prescription Drug plan shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a community pharmacy, rather than through mail order, and may permit a differential amount to be paid by such enrollees.

“(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If an eligible entity offering a Medicare Prescription Drug plan uses a formulary, the following requirements must be met:

“(A) PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—

“(i) IN GENERAL.—The eligible entity must establish a pharmacy and therapeutic committee that develops and reviews the formulary.

“(ii) COMPOSITION.—A pharmacy and therapeutic committee shall include at least 1 academic expert, at least 1 practicing physician, and at least 1 practicing pharmacist, all of whom have expertise in the care of elderly or disabled persons, and a

majority of the members of such committee shall consist of individuals who are a practicing physician or a practicing pharmacist (or both).

“(B) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate.

“(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES AND CLASSES.—

“(i) IN GENERAL.—The formulary must include drugs within each therapeutic category and class of covered drugs (as defined by the Administrator), although not necessarily for all drugs within such categories and classes.

“(ii) REQUIREMENT.—In defining therapeutic categories and classes of covered drugs pursuant to clause (i), the Administrator shall use—

“(I) the compendia referred to
section 1927(g)(1)(B)(i); and

“(II) other recognized sources of
drug classifications and categoriza-
tions determined appropriate by the
Administrator.

“(D) PROVIDER EDUCATION.—The com-
mittee shall establish policies and procedures to
educate and inform health care providers con-
cerning the formulary.

“(E) NOTICE BEFORE REMOVING DRUGS
FROM FORMULARY.—Any removal of a drug
from a formulary shall take effect only after ap-
propriate notice is made available to bene-
ficiaries, physicians, and pharmacists.

“(F) APPEALS AND EXCEPTIONS TO APPLI-
CATION.—The eligible entity must have, as part
of the appeals process under subsection (e), a
process for timely appeals for denials of cov-
erage based on such application of the for-
mulary.

“(g) COST AND UTILIZATION MANAGEMENT; QUAL-
ITY ASSURANCE; MEDICATION THERAPY MANAGEMENT
PROGRAM.—

1 “(1) IN GENERAL.—An eligible entity shall have
2 in place the following with respect to covered drugs:

3 “(A) A cost-effective drug utilization man-
4 agement program, including incentives to re-
5 duce costs when appropriate.

6 “(B) Quality assurance measures to reduce
7 medical errors and adverse drug interactions
8 and to improve medication use, which—

9 “(i) shall include a medication therapy
10 management program described in para-
11 graph (2); and

12 “(ii) may include beneficiary edu-
13 cation programs, counseling, medication
14 refill reminders, and special packaging.

15 “(C) A program to control fraud, abuse,
16 and waste.

17 Nothing in this section shall be construed as impair-
18 ing an eligible entity from applying cost manage-
19 ment tools (including differential payments) under
20 all methods of operation.

21 “(2) MEDICATION THERAPY MANAGEMENT PRO-
22 GRAM.—

23 “(A) IN GENERAL.—A medication therapy
24 management program described in this para-
25 graph is a program of drug therapy manage-

ment and medication administration that is designed to assure, with respect to beneficiaries with chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure) or multiple prescriptions, that covered drugs under the Medicare Prescription Drug plan are appropriately used to optimize therapeutic outcomes through improved medication use and to achieve therapeutic goals and reduce the risk of adverse events, including adverse drug interactions.

“(B) ELEMENTS.—Such program may include—

“(i) enhanced beneficiary understanding of such appropriate use through beneficiary education, counseling, and other appropriate means;

“(ii) increased beneficiary adherence with prescription medication regimens through medication refill reminders, special packaging, and other appropriate means; and

“(iii) detection of patterns of overuse and underuse of prescription drugs.

1 “(C) DEVELOPMENT OF PROGRAM IN CO-
2 OPERATION WITH LICENSED PHARMACISTS.—

3 The program shall be developed in cooperation
4 with licensed and practicing pharmacists and
5 physicians.

6 “(D) CONSIDERATIONS IN PHARMACY
7 FEES.—The eligible entity offering a Medicare
8 Prescription Drug plan shall take into account,
9 in establishing fees for pharmacists and others
10 providing services under the medication therapy
11 management program, the resources and time
12 used in implementing the program.

13 “(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL
14 PRICES FOR EQUIVALENT DRUGS.—The eligible enti-
15 ty offering a Medicare Prescription Drug plan shall
16 provide that each pharmacy or other dispenser that
17 arranges for the dispensing of a covered drug shall
18 inform the beneficiary at the time of purchase of the
19 drug of any differential between the price of the pre-
20 scribed drug to the enrollee and the price of the low-
21 est cost generic drug covered under the plan that is
22 therapeutically equivalent and bioequivalent.

23 “(d) GRIEVANCE MECHANISM, COVERAGE DETER-
24 MINATIONS, AND RECONSIDERATIONS.—

1 “(1) IN GENERAL.—An eligible entity shall pro-
2 vide meaningful procedures for hearing and resolving
3 grievances between the eligible entity (including any
4 entity or individual through which the eligible entity
5 provides covered benefits) and enrollees with Medi-
6 care Prescription Drug plans of the eligible entity
7 under this part in accordance with section 1852(f).

8 “(2) APPLICATION OF COVERAGE DETERMINA-
9 TION AND RECONSIDERATION PROVISIONS.—The re-
10 quirements of paragraphs (1) through (3) of section
11 1852(g) shall apply to an eligible entity with respect
12 to covered benefits under the Medicare Prescription
13 Drug plan it offers under this part in the same man-
14 ner as such requirements apply to a
15 MedicareAdvantage organization with respect to ben-
16 efits it offers under a MedicareAdvantage plan
17 under part C. *1852(g)(1)(B)(i) shall apply.*

18 “(3) REQUEST FOR REVIEW OF TIERED FOR-
19 MULARY DETERMINATIONS.—In the case of a Medi-
20 care Prescription Drug plan offered by an eligible
21 entity that provides for tiered cost-sharing for drugs
22 included within a formulary and provides lower cost-
23 sharing for preferred drugs included within the for-
24 mulary, an individual who is enrolled in the plan
25 may request coverage of a nonpreferred drug under

1 the terms applicable for preferred drugs if the pre-
2 scribing physician determines that the preferred
3 drug for treatment of the same condition is not as
4 effective for the individual or has adverse effects for
5 the individual.

6 “(e) APPEALS.—

7 “(1) IN GENERAL.—Subject to paragraph (2),
8 the requirements of paragraphs (4) and (5) of sec-
9 tion 1852(g) shall apply to an eligible entity with re-
10 spect to drugs not included on any formulary in a
11 manner that is similar (as determined by the Admin-
12 istrator) to the manner that such requirements
13 apply to a MedicareAdvantage organization with re-
14 spect to benefits it offers under a
15 MedicareAdvantage plan under part C.

16 “(2) FORMULARY DETERMINATIONS.—An indi-
17 vidual who is enrolled in a Medicare Prescription
18 Drug plan offered by an eligible entity may appeal
19 to obtain coverage for a covered drug that is not on
20 a formulary of the entity under the terms applicable
21 for a formulary drug if the prescribing physician de-
22 termines that the formulary drug for treatment of
23 the same condition is not as effective for the indi-
24 vidual or has adverse effects for the individual.

1 “(f) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF
2 ENROLLEE RECORDS.—Insofar as an eligible entity main-
3 tains individually identifiable medical records or other
4 health information regarding eligible beneficiaries enrolled
5 in the Medicare Prescription Drug plan offered by the en-
6 tity, the entity shall have in place procedures to—

7 “(1) safeguard the privacy of any individually
8 identifiable beneficiary information in a manner con-
9 sistent with the Federal regulations (concerning the
10 privacy of individually identifiable health informa-
11 tion) promulgated under section 264(c) of the
12 Health Insurance Portability and Accountability Act
13 of 1996;

14 “(2) maintain such records and information in
15 a manner that is accurate and timely;

16 “(3) ensure timely access by such beneficiaries
17 to such records and information; and

18 “(4) otherwise comply with applicable laws re-
19 lating to patient privacy and confidentiality.

20 “(g) UNIFORM MONTHLY PLAN PREMIUM.—An eligi-
21 ble entity shall ensure that the monthly plan premium for
22 a Medicare Prescription Drug plan charged under this
23 part is the same for all eligible beneficiaries enrolled in
24 the plan. Such requirement shall not apply to enrollees
25 of a Medicare Prescription Drug plan who are enrolled in

1 the plan pursuant to a contractual agreement between the
 2 plan and an employer or other group health plan that pro-
 3 vides employment-based retiree health coverage (as de-
 4 fined in section 1860D-20(d)(4)(B)) if the premium
 5 amount is the same for all such enrollees under such
 6 agreement.

7 “(h) CONSUMER SATISFACTION SURVEYS.—An eligi-
 8 ble entity shall conduct consumer satisfaction surveys with
 9 respect to the plan and the entity. The Administrator shall
 10 establish uniform requirements for such surveys.

11 “PRESCRIPTION DRUG BENEFITS

12 “SEC. 1860D-6. (a) REQUIREMENTS.—

13 “(1) IN GENERAL.—For purposes of this part
 14 and part C, the term ‘qualified prescription drug
 15 coverage’ means either of the following:

16 “(A) STANDARD PRESCRIPTION DRUG COV-
 17 ERAGE WITH ACCESS TO NEGOTIATED
 18 PRICES.—Standard prescription drug coverage
 19 (as defined in subsection (c)) and access to ne-
 20 gotiated prices under subsection (e).

21 “(B) ACTUARIALLY EQUIVALENT PRE-
 22SCRIPTION DRUG COVERAGE WITH ACCESS TO
 23 NEGOTIATED PRICES.—Coverage of covered
 24 drugs which meets the alternative coverage re-
 25 quirements of subsection (d) and access to ne-
 26 gotiated prices under subsection (e), but only if

1 it is approved by the Administrator as provided
2 under subsection (d).

3 “(2) PERMITTING ADDITIONAL PRESCRIPTION
4 DRUG COVERAGE.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graph (B) and section 1860D–13(c)(2), nothing
7 in this part shall be construed as preventing
8 qualified prescription drug coverage from in-
9 cluding coverage of covered drugs that exceeds
10 the coverage required under paragraph (1).

11 “(B) REQUIREMENT.—An eligible entity
12 may not offer a Medicare Prescription Drug
13 plan that provides additional benefits pursuant
14 to subparagraph (A) in an area unless the eligi-
15 ble entity offering such plan also offers a Medi-
16 care Prescription Drug plan in the area that
17 only provides the coverage of prescription drugs
18 that is required under paragraph (1).

19 “(3) COST CONTROL MECHANISMS.—In pro-
20 viding qualified prescription drug coverage, the enti-
21 ty offering the Medicare Prescription Drug plan or
22 the Medicare Advantage plan may use a variety of
23 cost control mechanisms, including the use of
24 formularies, tiered copayments, selective contracting

1 with providers of prescription drugs, and mail order
2 pharmacies.

3 “(b) APPLICATION OF SECONDARY PAYOR PROVI-
4 SIONS.—The provisions of section 1852(a)(4) shall apply
5 under this part in the same manner as they apply under
6 part C.

7 “(c) STANDARD PRESCRIPTION DRUG COVERAGE.—
8 For purposes of this part and part C, the term ‘standard
9 prescription drug coverage’ means coverage of covered
10 drugs that meets the following requirements:

11 “(1) DEDUCTIBLE.—

12 “(A) IN GENERAL.—The coverage has an
13 annual deductible—

14 “(i) for 2006, that is equal to \$275;

15 or

16 “(ii) for a subsequent year, that is
17 equal to the amount specified under this
18 paragraph for the previous year increased
19 by the percentage specified in paragraph
20 (5) for the year involved.

21 “(B) ROUNDING.—Any amount determined
22 under subparagraph (A)(ii) that is not a mul-
23 tiple of \$1 shall be rounded to the nearest mul-
24 tiple of \$1.

“(2) LIMITS ON COST-SHARING.—The coverage has cost-sharing (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is equal to 50 percent or that is actuarially consistent (using processes established under subsection (f)) with an average expected payment of 50 percent of such costs.

“(3) INITIAL COVERAGE LIMIT.—

“(A) IN GENERAL.—Subject to paragraph (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)—

“(i) for 2006, that is equal to \$4,500;

or

“(ii) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (5) for the year involved.

“(B) ROUNDING.—Any amount determined under subparagraph (A)(ii) that is not a multiple of \$1 shall be rounded to the nearest multiple of \$1.

1 “(4) LIMITATION ON OUT-OF-POCKET EXPENDI-
2 TURES BY BENEFICIARY.—

3 “(A) IN GENERAL.—The coverage provides
4 benefits with cost-sharing that is equal to 10
5 percent after the individual has incurred costs
6 (as described in subparagraph (C)) for covered
7 drugs in a year equal to the annual out-of-pock-
8 et limit specified in subparagraph (B).

9 “(B) ANNUAL OUT-OF-POCKET LIMIT.—

10 “(i) IN GENERAL.—For purposes of
11 this part, the ‘annual out-of-pocket limit’
12 specified in this subparagraph—

13 “(I) for 2006, is equal to \$3,700;
14 or

15 “(II) for a subsequent year, is
16 equal to the amount specified in this
17 subparagraph for the previous year,
18 increased by the annual percentage in-
19 crease described in paragraph (5) for
20 the year involved.

21 “(ii) ROUNDING.—Any amount deter-
22 mined under clause (i)(II) that is not a
23 multiple of \$1 shall be rounded to the
24 nearest multiple of \$1.

1 “(C) APPLICATION.—In applying subpara-
2 graph (A)—

3 “(i) incurred costs shall only include
4 costs incurred, with respect to covered
5 drugs, for the annual deductible (described
6 in paragraph (1)), cost-sharing (described
7 in paragraph (2)), and amounts for which
8 benefits are not provided because of the
9 application of the initial coverage limit de-
10 scribed in paragraph (3) (including costs
11 incurred for covered drugs described in
12 section 1860D(a)(2)(C)); and

13 “(ii) such costs shall be treated as in-
14 curred only if they are paid by the indi-
15 vidual (or by another individual, such as a
16 family member, on behalf of the indi-
17 vidual), under section 1860D–19 (but only
18 with respect to the percentage of such
19 costs that the individual is responsible for
20 under that section), under title XIX, or
21 under a State pharmaceutical assistance
22 program and the individual (or other indi-
23 vidual) is not reimbursed through insur-
24 ance or otherwise, a group health plan, or

1 other third-party payment arrangement for
2 such costs.

3 “(D) INFORMATION REGARDING THIRD-
4 PARTY REIMBURSEMENT.—In order to ensure
5 compliance with the requirements of subpara-
6 graph (C)(ii), the Administrator is authorized
7 to establish procedures, in coordination with the
8 Secretary of Treasury and the Secretary of
9 Labor, for determining whether costs for indi-
10 viduals are being reimbursed through insurance
11 or otherwise, a group health plan, or other
12 third-party payment arrangement, and for
13 alerting the entities in which such individuals
14 are enrolled about such reimbursement arrange-
15 ments. An entity with a contract under this
16 part may also periodically ask individuals en-
17 rolled in a plan offered by the entity whether
18 the individuals have or expect to receive such
19 third-party reimbursement. A material mis-
20 representation of the information described in
21 the preceding sentence by an individual (as de-
22 fined in standards set by the Administrator and
23 determined through a process established by the
24 Administrator) shall constitute grounds for ter-

mination of enrollment under section 1860D-
2(d).

“(5) ANNUAL PERCENTAGE INCREASE.—For
purposes of this part, the annual percentage increase
specified in this paragraph for a year is equal to the
annual percentage increase in average per capita ag-
gregate expenditures for covered drugs in the United
States for beneficiaries under this title, as deter-
mined by the Administrator for the 12-month period
ending in July of the previous year.

“(d) ALTERNATIVE COVERAGE REQUIREMENTS.—A
Medicare Prescription Drug plan or Medicare Advantage
plan may provide a different prescription drug benefit de-
sign from the standard prescription drug coverage de-
scribed in subsection (c) so long as the Administrator de-
termines (based on an actuarial analysis by the Adminis-
trator) that the following requirements are met and the
plan applies for, and receives, the approval of the Adminis-
trator for such benefit design: *substantially equivalent*

“(1) ASSURING AT LEAST ACTUARIALLY EQUIV-
ALENT PRESCRIPTION DRUG COVERAGE.—

“(A) ASSURING EQUIVALENT VALUE OF
TOTAL COVERAGE.—The actuarial value of the
total coverage (as determined under subsection
(f)) is at least equal to the actuarial value (as

1 so determined) of standard prescription drug
2 coverage.

3 “(B) ASSURING EQUIVALENT UNSUB-
4 SIDIZED VALUE OF COVERAGE.—The unsub-
5 sidized value of the coverage is at least equal to
6 the unsubsidized value of standard prescription
7 drug coverage. For purposes of this subpara-
8 graph, the unsubsidized value of coverage is the
9 amount by which the actuarial value of the cov-
10 erage (as determined under subsection (f)) ex-
11 ceeds the actuarial value of the amounts associ-
12 ated with the application of section 1860D-
13 17(c) and reinsurance payments under section
14 1860D-20 with respect to such coverage.

15 “(C) ASSURING STANDARD PAYMENT FOR
16 COSTS AT INITIAL COVERAGE LIMIT.—The cov-
17 erage is designed, based upon an actuarially
18 representative pattern of utilization (as deter-
19 mined under subsection (f)), to provide for the
20 payment, with respect to costs incurred that are
21 equal to the initial coverage limit under sub-
22 section (c)(3), of an amount equal to at least
23 the product of—

24 “(i) such initial coverage limit minus
25 the deductible under subsection (c)(1); and

“(ii) the percentage specified in subsection (c)(2).

Benefits other than qualified prescription drug coverage shall not be taken into account for purposes of this paragraph.

“(2) DEDUCTIBLE AND LIMITATION ON OUT-OF-POCKET EXPENDITURES BY BENEFICIARIES MAY NOT VARY.—The coverage may not vary the deductible under subsection (c)(1) for the year or the limitation on out-of-pocket expenditures by beneficiaries described in subsection (c)(4) for the year.

“(e) ACCESS TO NEGOTIATED PRICES.—

“(1) ACCESS.—

“(A) IN GENERAL.—Under qualified prescription drug coverage offered by an eligible entity or a MedicareAdvantage organization, the entity or organization shall provide beneficiaries with access to negotiated prices used for payment for covered drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of the deductible, any cost-sharing, or an initial coverage limit (described in subsection (c)(3)). For purposes of this part, the term ‘negotiated prices’ includes all dis-

counts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations.

“(B) MEDICAID RELATED PROVISIONS.—
Insofar as a State elects to provide medical assistance under title XIX for a drug based on the prices negotiated under a Medicare Prescription Drug plan under this part—

“(i) the medical assistance for such a drug shall be disregarded for purposes of a rebate agreement entered into under section 1927 which would otherwise apply to the provision of medical assistance for the drug under title XIX; and

“(ii) the prices negotiated under a Medicare Prescription Drug plan with respect to covered drugs, under a Medicare Advantage plan with respect to such drugs, or under a qualified retiree prescription drug plan (as defined in section 1860D–20(e)(4)) with respect to such drugs, on behalf of eligible beneficiaries, shall (notwithstanding any other provision of law) not be taken into account for the

1 purposes of establishing the best price
2 under section 1927(c)(1)(C).

3 “(2) CARDS OR OTHER TECHNOLOGY.—

4 “(A) IN GENERAL.—In providing the ac-
5 cess under paragraph (1), the eligible entity or
6 MedicareAdvantage organization shall issue a
7 card or use other technology pursuant to sec-
8 tion 1860D–5(b)(1).

9 “(B) NATIONAL STANDARDS.—

10 “(i) DEVELOPMENT.—The Adminis-
11 trator shall provide for the development of
12 national standards relating to a standard-
13 ized format for the card or other tech-
14 nology required under subparagraph (A).
15 Such standards shall be compatible with
16 parts C and D of title XI and may be
17 based on standards developed by an appro-
18 priate standard setting organization.

19 “(ii) CONSULTATION.—In developing
20 the standards under clause (i), the Admin-
21 istrator shall consult with the National
22 Council for Prescription Drug Programs
23 and other standard-setting organizations
24 determined appropriate by the Adminis-
25 trator.

1 “(iii) IMPLEMENTATION.—The Ad-
2 ministrator shall implement the standards
3 developed under clause (i) by January 1,
4 2008.

5 “(3) DISCLOSURE.—The eligible entity offering
6 a Medicare Prescription Drug plan and the
7 MedicareAdvantage organization offering a
8 MedicareAdvantage plan shall disclose to the Admin-
9 istrator (in a manner specified by the Administrator)
10 the extent to which discounts, direct or indirect sub-
11 sidies, rebates, or other price concessions or direct or
12 indirect remunerations made available to the entity
13 or organization by a manufacturer are passed
14 through to enrollees through pharmacies and other
15 dispensers or otherwise. The provisions of section
16 1927(b)(3)(D) shall apply to information disclosed
17 to the Administrator under this paragraph in the
18 same manner as such provisions apply to informa-
19 tion disclosed under such section.

20 “(4) AUDITS AND REPORTS.—To protect
21 against fraud and abuse and to ensure proper disclo-
22 sures and accounting under this part, in addition to
23 any protections against fraud and abuse provided
24 under section 1860D–7(f)(1), the Administrator may
25 periodically audit the financial statements and

records of an eligible entity offering a Medicare Prescription Drug plan and a Medicare Advantage organization offering a Medicare Advantage plan with the auditor of the Administrator's choice.

“(f) ACTUARIAL VALUATION; DETERMINATION OF ANNUAL PERCENTAGE INCREASES.—

“(1) PROCESSES.—For purposes of this section, the Administrator shall establish processes and methods—

“(A) for determining the actuarial valuation of prescription drug coverage, including—

“(i) an actuarial valuation of standard prescription drug coverage and of the reinsurance payments under section 1860D-20;

“(ii) the use of generally accepted actuarial principles and methodologies; and

“(iii) applying the same methodology for determinations of alternative coverage under subsection (d) as is used with respect to determinations of standard prescription drug coverage under subsection (c); and

“(B) for determining annual percentage increases described in subsection (c)(5).

1 Such processes shall take into account any effect
 2 that providing actuarially equivalent prescription
 3 drug coverage rather than standard prescription
 4 drug coverage has on drug utilization.

5 “(2) USE OF OUTSIDE ACTUARIES.—Under the
 6 processes under paragraph (1)(A), eligible entities
 7 and MedicareAdvantage organizations may use actu-
 8 arial opinions certified by independent, qualified ac-
 9 tuaries to establish actuarial values, but the Admin-
 10 istrator shall determine whether such actuarial val-
 11 ues meet the requirements under subsection (c)(1).

12 “REQUIREMENTS FOR ENTITIES OFFERING MEDICARE
 13 PRESCRIPTION DRUG PLANS; ESTABLISHMENT OF
 14 STANDARDS

15 “SEC. 1860D-7. (a) GENERAL REQUIREMENTS.—An
 16 eligible entity offering a Medicare Prescription Drug plan
 17 shall meet the following requirements:

18 “(1) LICENSURE.—Subject to subsection (c),
 19 the entity is organized and licensed under State law
 20 as a risk-bearing entity eligible to offer health insur-
 21 ance or health benefits coverage in each State in
 22 which it offers a Medicare Prescription Drug plan.

23 “(2) ASSUMPTION OF FINANCIAL RISK.—

24 “(A) IN GENERAL.—Subject to subpara-
 25 graph (B) and subsections (d)(2) and (e) of
 26 section 1860D-13, to the extent that the entity

1 is at risk pursuant to such section 1860D-16,
2 the entity assumes financial risk on a prospec-
3 tive basis for the benefits that it offers under
4 a Medicare Prescription Drug plan and that is
5 not covered under section 1860D-20.

6 “(B) REINSURANCE PERMITTED.—To the
7 extent that the entity is at risk pursuant to sec-
8 tion 1860D-16, the entity may obtain insur-
9 ance or make other arrangements for the cost
10 of coverage provided to any enrolled member
11 under this part. 12 13 14 15 16 17 18 19 20 21 22 23 24 25

12 “(3) SOLVENCY FOR UNLICENSED ENTITIES.—

13 In the case of an eligible entity that is not described
14 in paragraph (1) and for which a waiver has been
15 approved under subsection (c), such entity shall
16 meet solvency standards established by the Adminis-
17 trator under subsection (d).

18 “(b) CONTRACT REQUIREMENTS.—The Adminis-
19 trator shall not permit an eligible beneficiary to elect a
20 Medicare Prescription Drug plan offered by an eligible en-
21 tity under this part, and the entity shall not be eligible
22 for payments under section 1860D-16 or 1860D-20, un-
23 less the Administrator has entered into a contract under
24 this subsection with the entity with respect to the offering
25 of such plan. Such a contract with an entity may cover

1 more than 1 Medicare Prescription Drug plan. Such con-
 2 tract shall provide that the entity agrees to comply with
 3 the applicable requirements and standards of this part and
 4 the terms and conditions of payment as provided for in
 5 this part.

6 “(c) WAIVER OF CERTAIN REQUIREMENTS IN ORDER
 7 TO ENSURE BENEFICIARY CHOICE.—

8 “(1) IN GENERAL.—In the case of an eligible
 9 entity that seeks to offer a Medicare Prescription
 10 Drug plan in a State, the Administrator shall waive
 11 the requirement of subsection (a)(1) that the entity
 12 be licensed in that State if the Administrator deter-
 13 mines, based on the application and other evidence
 14 presented to the Administrator, that any of the
 15 grounds for approval of the application described in
 16 paragraph (2) have been met.

17 “(2) GROUNDS FOR APPROVAL.—The grounds
 18 for approval under this paragraph are the grounds
 19 for approval described in subparagraphs (B), (C),
 20 and (D) of section 1855(a)(2), and also include the
 21 application by a State of any grounds other than
 22 those required under Federal law.

23 “(3) APPLICATION OF WAIVER PROCEDURES.—
 24 With respect to an application for a waiver (or a
 25 waiver granted) under this subsection, the provisions

of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply.

“(4) REFERENCES TO CERTAIN PROVISIONS.—

For purposes of this subsection, in applying the provisions of section 1855(a)(2) under this subsection to Medicare Prescription Drug plans and eligible entities—

“(A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1); and

“(B) any reference to solvency standards were treated as a reference to solvency standards established under subsection (d).

“(d) SOLVENCY STANDARDS FOR NON-LICENSED ENTITIES.—

“(1) ESTABLISHMENT AND PUBLICATION.—The Administrator, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

“(2) COMPLIANCE WITH STANDARDS.—An eligible entity that is not licensed by a State under subsection (a)(1) and for which a waiver application has

1 been approved under subsection (c) shall meet sol-
 2 vency and capital adequacy standards established
 3 under paragraph (1). The Administrator shall estab-
 4 lish certification procedures for such eligible entities
 5 with respect to such solvency standards in the man-
 6 ner described in section 1855(c)(2).

7 “(e) LICENSURE DOES NOT SUBSTITUTE FOR OR
 8 CONSTITUTE CERTIFICATION.—The fact that an entity is
 9 licensed in accordance with subsection (a)(1) or has a
 10 waiver application approved under subsection (c) does not
 11 deem the eligible entity to meet other requirements im-
 12 posed under this part for an eligible entity.

13 “(f) INCORPORATION OF CERTAIN
 14 MEDICAREADVANTAGE CONTRACT REQUIREMENTS.—The
 15 following provisions of section 1857 shall apply, subject
 16 to subsection (c)(4), to contracts under this section in the
 17 same manner as they apply to contracts under section
 18 1857(a):

19 “(1) PROTECTIONS AGAINST FRAUD AND BENE-
 20 FICIARY PROTECTIONS.—Section 1857(d).

21 “(2) INTERMEDIATE SANCTIONS.—Section
 22 1857(g), except that in applying such section—

23 “(A) the reference in section
 24 1857(g)(1)(B) to section 1854 is deemed a ref-
 25 erence to this part; and

“(B) the reference in section 1857(g)(1)(F) to section 1852(k)(2)(A)(ii) shall not be applied.

“(3) PROCEDURES FOR TERMINATION.—Section 1857(h).

“(g) OTHER STANDARDS.—The Administrator shall establish by regulation other standards (not described in subsection (d)) for eligible entities and Medicare Prescription Drug plans consistent with, and to carry out, this part. The Administrator shall publish such regulations by January 1, 2005.

“(h) PERIODIC REVIEW AND REVISION OF STANDARDS.—

“(1) IN GENERAL.—Subject to paragraph (2), the Administrator shall periodically review the standards established under this section and, based on such review, may revise such standards if the Administrator determines such revision to be appropriate.

“(2) PROHIBITION OF MIDYEAR IMPLEMENTATION OF SIGNIFICANT NEW REGULATORY REQUIREMENTS.—The Administrator may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, signifi-

1 cant regulatory requirements on an eligible entity or
2 a Medicare Prescription Drug plan.

3 “(h) RELATION TO STATE LAWS.—

4 “(1) IN GENERAL.—The standards established
5 under this part shall supersede any State law or reg-
6 ulation (including standards described in paragraph
7 (2)) with respect to Medicare Prescription Drug
8 plans which are offered by eligible entities under this
9 part—

10 “(A) to the extent such law or regulation
11 is inconsistent with such standards; and

12 “(B) in the same manner as such laws and
13 regulations are superseded under section
14 1856(b)(3).

15 “(2) STANDARDS SPECIFICALLY SUPER-
16 SEDED.—State standards relating to the following
17 are superseded under this section:

18 “(A) Benefit requirements, including re-
19 quirements relating to cost-sharing and the
20 structure of formularies.

21 “(B) Premiums.

22 “(C) Requirements relating to inclusion or
23 treatment of providers.

24 “(D) Coverage determinations (including
25 related appeals and grievance processes).

“(E) Requirements relating to marketing materials and summaries and schedules of benefits regarding a Medicare Prescription Drug plan.

“(3) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES.—No State may impose a premium tax or similar tax with respect to—

“(A) monthly beneficiary obligations paid to the Administrator for Medicare Prescription Drug plans under this part; or

“(B) any payments made by the Administrator under this part to an eligible entity offering such a plan.

“Subpart 2—Prescription Drug Delivery System

“ESTABLISHMENT OF SERVICE AREAS

“SEC. 1860D-10. (a) ESTABLISHMENT.—

“(1) INITIAL ESTABLISHMENT.—Not later than April 15, 2005, the Administrator shall establish and publish the service areas in which Medicare Prescription Drug plans may offer benefits under this part.

“(2) PERIODIC REVIEW AND REVISION OF SERVICE AREAS.—The Administrator shall periodically review the service areas applicable under this section and, based on such review, may revise such

1 service areas if the Administrator determines such
2 revision to be appropriate.

3 “(b) REQUIREMENTS FOR ESTABLISHMENT OF
4 SERVICE AREAS.—

5 “(1) IN GENERAL.—The Administrator shall es-
6 tablish the service areas under subsection (a) in a
7 manner that—

8 “(A) maximizes the availability of Medi-
9 care Prescription Drug plans to eligible bene-
10 ficiaries; and

11 “(B) minimizes the ability of eligible enti-
12 ties offering such plans to favorably select eligi-
13 ble beneficiaries.

14 “(2) ADDITIONAL REQUIREMENTS.—The Ad-
15 ministrator shall establish the service areas under
16 subsection (a) consistent with the following require-
17 ments:

18 “(A) There shall be at least 10 service
19 areas.

20 “(B) Each service area must include at
21 least 1 State.

22 “(C) The Administrator may not divide
23 States so that portions of the State are in dif-
24 ferent service areas.

“(D) To the extent possible, the Administrator shall include multistate metropolitan statistical areas in a single service area. The Administrator may divide metropolitan statistical areas where it is necessary to establish service areas of such size and geography as to maximize the participation of Medicare Prescription Drug plans.

“(3) MAY CONFORM TO MEDICAREADVANTAGE PREFERRED PROVIDER REGIONS.—The Administrator may conform the service areas established under this section to the preferred provider regions established under section 1858(a)(3).

“PUBLICATION OF RISK ADJUSTERS

“SEC. 1860D–11. (a) PUBLICATION.—Not later than April 15 of each year (beginning in 2005), the Administrator shall publish the risk adjusters established under subsection (b) to be used in computing—

“(1) the amount of payment to Medicare Prescription Drug plans in the subsequent year under section 1860D–16(a), insofar as it is attributable to standard prescription drug coverage (or actuarially equivalent prescription drug coverage); and

“(2) the amount of payment to MedicareAdvantage plans in the subsequent year under section 1858A(c), insofar as it is attributable

1 to standard prescription drug coverage (or actuari-
 2 ally equivalent prescription drug coverage). 5

3 “(b) ESTABLISHMENT OF RISK ADJUSTERS.—

4 “(1) IN GENERAL.—Subject to paragraph (2),
 5 the Administrator shall establish an appropriate
 6 methodology for adjusting the amount of payment to
 7 plans referred to in subsection (a) to take into ac-
 8 count variation in costs based on the differences in
 9 actuarial risk of different enrollees being served. Any
 10 such risk adjustment shall be designed in a manner
 11 as to not result in a change in the aggregate pay-
 12 ments described in paragraphs (1) and (2) of sub-
 13 section (a). 6739 103

14 “(2) CONSIDERATIONS.—In establishing the
 15 methodology under paragraph (1), the Administrator
 16 may take into account the similar methodologies
 17 used under section 1853(a)(3) to adjust payments to
 18 MedicareAdvantage organizations. 113 103000000

19 “(3) DATA COLLECTION.—In order to carry out
 20 this subsection, the Administrator shall require—

21 “(A) eligible entities to submit data re-
 22 garding drug claims that can be linked at the
 23 beneficiary level to part A and part B data and
 24 such other information as the Administrator de-
 25 termines necessary; and

1 “(B) MedicareAdvantage organizations
2 (except MSA plans or a private fee-for-service
3 plan that does not provide qualified prescription
4 drug coverage) to submit data regarding drug
5 claims that can be linked to other data that
6 such organizations are required to submit to
7 the Administrator and such other information
8 as the Administrator determines necessary.

9 “SUBMISSION OF BIDS FOR PROPOSED MEDICARE
10 PRESCRIPTION DRUG PLANS

11 “SEC. 1860D-12. (a) SUBMISSION.—

12 “(1) IN GENERAL.—Each eligible entity that in-
13 tends to offer a Medicare Prescription Drug plan in
14 an area in a year (beginning with 2006) shall submit
15 to the Administrator, at such time in the previous
16 year and in such manner as the Administrator may
17 specify, such information as the Administrator may
18 require, including the information described in sub-
19 section (b).

20 “(2) ANNUAL SUBMISSION.—An eligible entity
21 shall submit the information required under para-
22 graph (1) with respect to a Medicare Prescription
23 Drug plan that the entity intends to offer on an an-
24 nual basis.

1 “(b) INFORMATION DESCRIBED.—The information
2 described in this subsection includes information on each
3 of the following:

4 “(1) The benefits under the plan (as required
5 under section 1860D–6).

6 “(2) The actuarial value of the qualified pre-
7 scription drug coverage.

8 “(3) The amount of the monthly plan premium
9 under the plan, including an actuarial certification
10 of—

11 “(A) the actuarial basis for such monthly
12 plan premium;

13 “(B) the portion of such monthly plan pre-
14 mium attributable to standard prescription
15 drug coverage or actuarially equivalent prescrip-
16 tion drug coverage and, if applicable, to benefits
17 that are in addition to such coverage; and

18 “(C) the reduction in such monthly plan
19 premium resulting from the payments provided
20 under section 1860D–20.

21 “(4) The service area for the plan.

22 “(5) Whether the entity plans to use any funds
23 in the plan stabilization reserve fund in the Prescrip-
24 tion Drug Account that are available to the entity to
25 stabilize or reduce the monthly plan premium sub-

mitted under paragraph (3), and if so, the amount in such reserve fund that is to be used.

“(6) Such other information as the Administrator may require to carry out this part.

“(c) OPTIONS REGARDING SERVICE AREAS.—

“(1) IN GENERAL.—The service area of a Medicare Prescription Drug plan shall be either—

“(A) the entire area of 1 of the service areas established by the Administrator under section 1860D-10; or

“(B) the entire area covered by the Medicare program.

“(2) RULE OF CONSTRUCTION.—Nothing in this part shall be construed as prohibiting an eligible entity from submitting separate bids in multiple service areas as long as each bid is for a single service area.

“APPROVAL OF PROPOSED MEDICARE PRESCRIPTION DRUG PLANS

“SEC. 1860D-13. (a) APPROVAL.—

“(1) IN GENERAL.—The Administrator shall review the information filed under section 1860D-12 and shall approve or disapprove the Medicare Prescription Drug plan.

“(2) REQUIREMENTS FOR APPROVAL.—The Administrator may not approve a Medicare Prescrip-

1 tion Drug plan unless the following requirements are
2 met:

3 “(A) COMPLIANCE WITH REQUIRE-
4 MENTS.—The plan and the entity offering the
5 plan comply with the requirements under this
6 part.

7 “(B) APPLICATION OF FEHBP STAND-
8 ARD.—(i) The portion of the monthly plan pre-
9 mium submitted under section 1860D–12(b)
10 that is attributable to standard prescription
11 drug coverage reasonably and equitably reflects
12 the actuarial value of the standard prescription
13 drug coverage less the actuarial value of the re-
14 insurance payments under section 1860D–20
15 and the amount of any funds in the plan sta-
16 bilization reserve fund in the Prescription Drug
17 Account used to stabilize or reduce the monthly
18 plan premium.

19 “(ii) If the plan provides additional pre-
20 scription drug coverage pursuant to section
21 1860D–6(a)(2), the monthly plan premium rea-
22 sonably and equitably reflects the actuarial
23 value of the coverage provided less the actuarial
24 value of the reinsurance payments under section
25 1860D–20 and the amount of any funds in the

plan stabilization reserve fund in the Prescription Drug Account used to stabilize or reduce the monthly plan premium.

“(b) NEGOTIATION.—In exercising the authority under subsection (a), the Administrator shall have the authority to—

“(1) negotiate the terms and conditions of the proposed monthly plan premiums submitted and other terms and conditions of a proposed plan; and

“(2) disapprove, or limit enrollment in, a proposed plan based on—

“(A) the costs to beneficiaries under the plan;

“(B) the quality of the coverage and benefits under the plan;

“(C) the adequacy of the network under the plan;

“(D) the average aggregate projected cost of covered drugs under the plan relative to other Medicare Prescription Drug plans and Medicare Advantage plans; or

“(E) other factors determined appropriate by the Administrator.

“(c) SPECIAL RULES FOR APPROVAL.—The Administrator may approve a Medicare Prescription Drug plan

1 submitted under section 1860D-12 only if the benefits
2 under such plan—

3 “(1) include the required benefits under section
4 1860D-6(a)(1); and

5 “(2) are not designed in such a manner that
6 the Administrator finds is likely to result in favor-
7 able selection of eligible beneficiaries.

8 “(d) ACCESS TO COMPETITIVE COVERAGE.—

9 “(1) NUMBER OF CONTRACTS.—The Adminis-
10 trator, consistent with the requirements of this part
11 and the goal of containing costs under this title,
12 shall, with respect to a year, approve at least 2 con-
13 tracts to offer a Medicare Prescription Drug plan in
14 each service area (established under section 1860D-
15 10) for the year.

16 “(2) AUTHORITY TO REDUCE RISK TO ENSURE
17 ACCESS.—

18 “(A) IN GENERAL.—Subject to subpara-
19 graph (B), if the Administrator determines,
20 with respect to an area, that the access re-
21 quired under paragraph (1) is not going to be
22 provided in the area during the subsequent
23 year, the Administrator shall—

1 “(i) adjust the percents specified in
2 paragraphs (2) and (4) of section 1860D-
3 16(b) in an area in a year; or

4 “(ii) increase the percent specified in
5 section 1860D-20(c)(1) in an area in a
6 year.

7 The administrator shall exercise the authority
8 under the preceding sentence only so long as
9 (and to the extent) necessary to assure the ac-
10 cess guaranteed under paragraph (1).

11 “(B) REQUIREMENTS FOR USE OF AU-
12 THORITY.—In exercising authority under sub-
13 paragraph (A), the Administrator—

14 “(i) shall not provide for the full un-
15 derwriting of financial risk for any eligible
16 entity;

17 “(ii) shall not provide for any under-
18 writing of financial risk for a public eligi-
19 ble entity with respect to the offering of a
20 nationwide Medicare Prescription Drug
21 plan; and

22 “(iii) shall seek to maximize the as-
23 sumption of financial risk by eligible enti-
24 ties to ensure fair competition among
25 Medicare Prescription Drug plans.

1 “(C) REQUIREMENT TO ACCEPT 2 FULL-
 2 RISK QUALIFIED BIDS BEFORE EXERCISING AU-
 3 THORITY.—The Administrator may not exercise
 4 the authority under subparagraph (A) with re-
 5 spect to an area and year if 2 or more qualified
 6 bids are submitted by eligible entities to offer a
 7 Medicare Prescription Drug plan in the area for
 8 the year under paragraph (1) before the appli-
 9 cation of subparagraph (A).

10 “(D) REPORTS.—The Administrator, in
 11 each annual report to Congress under section
 12 1808(c)(1)(D), shall include information on the
 13 exercise of authority under subparagraph (A).
 14 The Administrator also shall include such rec-
 15 ommendations as may be appropriate to limit
 16 the exercise of such authority.

17 “(e) GUARANTEED ACCESS.—

18 “(1) ACCESS.—In order to assure access to
 19 qualified prescription drug coverage in an area, the
 20 Administrator shall take the following steps:

21 “(A) DETERMINATION.—Not later than
 22 September 1 of each year (beginning in 2005)
 23 and for each area (established under section
 24 1860D–10), the Administrator shall make a de-
 25 termination as to whether the access required

1 under subsection (d)(1) is going to be provided
2 in the area during the subsequent year. Such
3 determination shall be made after the Adminis-
4 trator has exercised the authority under sub-
5 section (d)(2). *UP/64*

6 “(B) CONTRACT WITH AN ENTITY TO PRO-
7 VIDE COVERAGE IN AN AREA.—Subject to para-
8 graph (3), if the Administrator makes a deter-
9 mination under subparagraph (A) that the ac-
10 cess required under subsection (d)(1) is not
11 going to be provided in an area during the sub-
12 sequent year, the Administrator shall enter into
13 a contract with an entity to provide eligible
14 beneficiaries enrolled under this part (and not,
15 except for an MSA plan or a private fee-for-
16 service plan that does not provide qualified pre-
17 scription drug coverage enrolled in a
18 MedicareAdvantage plan) and residing in the
19 area with standard prescription drug coverage
20 (including access to negotiated prices for such
21 beneficiaries pursuant to section 1860D–6(e))
22 during the subsequent year. An entity may be
23 awarded a contract for more than 1 of the
24 areas for which the Administrator is required to
25 enter into a contract under this paragraph but

1 the Administrator may enter into only 1 such
2 contract in each such area.

3 “(C) REQUIREMENT TO ACCEPT 2 RE-
4 DUCED-RISK QUALIFIED BIDS BEFORE ENTER-
5 ING INTO CONTRACT.—The Administrator may
6 not enter into a contract under subparagraph
7 (B) with respect to an area and year if 2 or
8 more qualified bids are submitted by eligible en-
9 tities to offer a Medicare Prescription Drug
10 plan in the area for the year after the Adminis-
11 trator has exercised the authority under sub-
12 section (d)(2) in the area for the year.

13 “(D) ENTITY REQUIRED TO MEET BENE-
14 FICIARY PROTECTION AND OTHER REQUIRE-
15 MENTS.—An entity with a contract under sub-
16 paragraph (B) shall meet the requirements de-
17 scribed in section 1860D–5 and such other re-
18 quirements determined appropriate by the Ad-
19 ministrator.

20 “(E) COMPETITIVE PROCEDURES.—Com-
21 petitive procedures (as defined in section 4(5)
22 of the Office of Federal Procurement Policy Act
23 (41 U.S.C. 403(5))) shall be used to enter into
24 a contract under subparagraph (B).

1 “(2) MONTHLY BENEFICIARY OBLIGATION FOR
2 ENROLLMENT.—

3 “(A) IN GENERAL.—In the case of an eligi-
4 ble beneficiary receiving access to qualified pre-
5 scription drug coverage through enrollment with
6 an entity with a contract under paragraph
7 (1)(B), the monthly beneficiary obligation of
8 such beneficiary for such enrollment shall be an
9 amount equal to the applicable percent (as de-
10 termined under section 1860D-17(c)) of the
11 monthly national average premium (as com-
12 puted under section 1860D-15) for the area for
13 the year, as adjusted using the geographic ad-
14 juster under subparagraph (B).

15 “(B) ESTABLISHMENT OF GEOGRAPHIC
16 ADJUSTER.—The Administrator shall establish
17 an appropriate methodology for adjusting the
18 monthly beneficiary obligation (as computed
19 under subparagraph (A)) for the year in an
20 area to take into account differences in drug
21 prices among areas. In establishing such meth-
22 odology, the Administrator may take into ac-
23 count differences in drug utilization between eli-
24 gible beneficiaries in an area and eligible bene-
25 ficiaries in other areas and the results of the

1 ongoing study required under section 106 of the
2 Prescription Drug and Medicare Improvement
3 Act of 2003. Any such adjustment shall be ap-
4 plied in a manner so as to not result in a
5 change in the aggregate payments made under
6 this part that would have been made if the Ad-
7 ministrator had not applied such adjustment.

8 “(3) PAYMENTS UNDER THE CONTRACT.—

9 “(A) IN GENERAL.—A contract entered
10 into under paragraph (1)(B) shall provide for—

11 “(i) payment for the negotiated costs
12 of covered drugs provided to eligible bene-
13 ficiaries enrolled with the entity; and

14 “(ii) payment of prescription manage-
15 ment fees that are tied to performance re-
16 quirements established by the Adminis-
17 trator for the management, administration,
18 and delivery of the benefits under the con-
19 tract.

20 “(B) PERFORMANCE REQUIREMENTS.—

21 The performance requirements established by
22 the Administrator pursuant to subparagraph
23 (A)(ii) shall include the following:

24 “(i) The entity contains costs to the
25 Prescription Drug Account and to eligible

beneficiaries enrolled under this part and
with the entity.

“(ii) The entity provides such beneficiaries with quality clinical care.

“(iii) The entity provides such beneficiaries with quality services.

“(C) ENTITY ONLY AT RISK TO THE EXTENT OF THE FEES TIED TO PERFORMANCE REQUIREMENTS.—An entity with a contract under paragraph (1)(B) shall only be at risk for the provision of benefits under the contract to the extent that the management fees paid to the entity are tied to performance requirements under subparagraph (A)(ii).

“(4) ELIGIBLE ENTITY THAT SUBMITTED A BID FOR THE AREA NOT ELIGIBLE TO BE AWARDED THE CONTRACT.—An eligible entity that submitted a bid to offer a Medicare Prescription Drug plan for an area for a year under section 1860D-12, including a bid submitted after the Administrator has exercised the authority under subsection (d)(2), may not be awarded a contract under paragraph (1)(B) for that area and year. The previous sentence shall apply to an entity that was awarded a contract under paragraph (1)(B) for the area in the previous

1 year and submitted such a bid under section
2 1860D-12 for the year.

3 “(5) TERM OF CONTRACT.—A contract entered
4 into under paragraph (1)(B) shall be for a 1-year
5 period. Such contract may provide for renewal at the
6 discretion of the Administrator if the Administrator
7 is required to enter into a contract under such para-
8 graph with respect to the area covered by such con-
9 tract for the subsequent year.

10 “(6) ENTITY NOT PERMITTED TO MARKET OR
11 BRAND THE CONTRACT.—An entity with a contract
12 under paragraph (1)(B) may not engage in any mar-
13 keting or branding of such contract.

14 “(7) RULES FOR AREAS WHERE ONLY 1 COM-
15 PETITIVELY BID PLAN WAS APPROVED.—In the case
16 of an area where (before the application of this sub-
17 section) only 1 Medicare Prescription Drug plan was
18 approved for a year—

19 “(A) the plan may (at the option of the
20 plan) be offered in the area for the year (under
21 rules applicable to such plans under this part
22 and not under this subsection);

23 “(B) eligible beneficiaries described in
24 paragraph (1)(B) may receive access to quali-
25 fied prescription drug coverage through enroll-

ment in the plan or with an entity with a contract under paragraph (1)(B); and

“(C) for purposes of applying section 1860D-3(a)(1)(A)(ii), such plan shall be the plan designated in the area under such section.

“(f) TWO-YEAR CONTRACTS.—Except for a contract entered into under subsection (e)(1)(B), a contract approved under this part shall be for a 2-year period.

“COMPUTATION OF MONTHLY STANDARD PRESCRIPTION DRUG COVERAGE PREMIUMS

“SEC. 1860D-14. (a) IN GENERAL.—For each year (beginning with 2006), the Administrator shall compute a monthly standard prescription drug coverage premium for each Medicare Prescription Drug plan approved under section 1860D-13 and for each Medicare Advantage plan.

“(b) REQUIREMENTS.—The monthly standard prescription drug coverage premium for a plan for a year shall be equal to—

“(1) in the case of a plan offered by an eligible entity or Medicare Advantage organization that provides standard prescription drug coverage or an actuarially equivalent prescription drug coverage and does not provide additional prescription drug coverage pursuant to section 1860D-6(a)(2), the monthly plan premium approved for the plan under section 1860D-13 for the year; and

1 “(2) in the case of a plan offered by an eligible
2 entity or MedicareAdvantage organization that pro-
3 vides additional prescription drug coverage pursuant
4 to section 1860D-6(a)(2)—

5 “(A) an amount that reflects only the actu-
6 arial value of the standard prescription drug
7 coverage offered under the plan; or

8 “(B) if determined appropriate by the Ad-
9 ministrator, the monthly plan premium ap-
10 proved under section 1860D-13 for the year for
11 the Medicare Prescription Drug plan (or, if ap-
12 plicable, the MedicareAdvantage plan) that, as
13 required under section 1860D-6(a)(2)(B) for a
14 Medicare Prescription Drug plans and a
15 MedicareAdvantage plan—

16 “(i) is offered by such entity or orga-
17 nization in the same area as the plan; and

18 “(ii) does not provide additional pre-
19 scription drug coverage pursuant to such
20 section.

21 “COMPUTATION OF MONTHLY NATIONAL AVERAGE
22 PREMIUM

23 “SEC. 1860D-15. (a) COMPUTATION.—

24 “(1) IN GENERAL.—For each year (beginning
25 with 2006) the Administrator shall compute a
26 monthly national average premium equal to the aver-

age of the monthly standard prescription drug coverage premium for each Medicare Prescription Drug plan and each Medicare Advantage plan (as computed under section 1860D-14). Such premium may be adjusted pursuant to any methodology determined under subsection (b), as determined appropriate by the Administrator.

“(2) WEIGHTED AVERAGE.—The monthly national average premium computed under paragraph (1) shall be a weighted average, with the weight for each plan being equal to the average number of beneficiaries enrolled under such plan in the previous year.

“(b) GEOGRAPHIC ADJUSTMENT.—The Administrator shall establish an appropriate methodology for adjusting the monthly national average premium (as computed under subsection (a)) for the year in an area to take into account differences in prices for covered drugs among different areas. In establishing such methodology, the Administrator may take into account differences in drug utilization between eligible beneficiaries in that area and other eligible beneficiaries and the results of the ongoing study required under section 106 of the Prescription Drug and Medicare Improvement Act of 2003. Any such adjustment shall be applied in a manner as to not result in a

1 change in aggregate payments made under this part than
 2 would have been made if the Administrator had not ap-
 3 plied such adjustment.

4 “(c) SPECIAL RULE FOR 2006.—For purposes of ap-
 5 plying this section for 2006, the Administrator shall estab-
 6 lish procedures for determining the weighted average
 7 under subsection (a)(2) for 2005.

8 “PAYMENTS TO ELIGIBLE ENTITIES

9 “SEC. 1860D-16. (a) PAYMENT OF MONTHLY PLAN
 10 PREMIUMS.—For each year (beginning with 2006), the
 11 Administrator shall pay to each entity offering a Medicare
 12 Prescription Drug plan in which an eligible beneficiary is
 13 enrolled an amount equal to the full amount of the month-
 14 ly plan premium approved for the plan under section
 15 1860D-13 on behalf of each eligible beneficiary enrolled
 16 in such plan for the year, as adjusted using the risk ad-
 17 justers that apply to the standard prescription drug cov-
 18 erage published under section 1860D-11.

19 “(b) PORTION OF TOTAL PAYMENTS OF MONTHLY
 20 PLAN PREMIUMS SUBJECT TO RISK.—

21 “(1) NOTIFICATION OF SPENDING UNDER THE
 22 PLAN.—

23 “(A) IN GENERAL.—For each year (begin-
 24 ning in 2007), the eligible entity offering a
 25 Medicare Prescription Drug plan shall notify
 26 the Administrator of the following:

“(i) TOTAL ACTUAL COSTS.—The total amount of costs that the entity incurred in providing standard prescription drug coverage (or prescription drug coverage that is actuarially equivalent pursuant to section 1860D–6(a)(1)(B)) for all enrollees under the plan in the previous year.

“(ii) AMOUNTS RESULTING IN ACTUAL COSTS.—With respect to the total amount under clause (i) for the year—

“(I) the aggregate amount of payments made by the entity to pharmacies and other entities with respect to such coverage for such enrollees; and

“(II) the aggregate amount of discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made to the entity with respect to such coverage for such enrollees.

“(B) CERTAIN EXPENSES NOT INCLUDED.—The amount under subparagraph (A)(i) may not include—

1 “(i) administrative expenses incurred
2 in providing the coverage described in sub-
3 paragraph (A)(i);

4 “(ii) amounts expended on providing
5 additional prescription drug coverage pur-
6 suant to section 1860D-6(a)(2);

7 “(iii) amounts expended for which the
8 entity is subsequently provided with rein-
9 surance payments under section 1860D-
10 20; or

11 “(iv) discounts, direct or indirect sub-
12 sidies, rebates, or other price concessions
13 or direct or indirect remunerations made
14 to the entity with respect to coverage de-
15 scribed in subparagraph (A)(i).

16 “(2) ADJUSTMENT OF PAYMENT.—

17 “(A) NO ADJUSTMENT IF ALLOWABLE
18 COSTS WITHIN RISK CORRIDOR.—If the allow-
19 able costs (specified in paragraph (3)) for the
20 plan for the year are not more than the first
21 threshold upper limit of the risk corridor (speci-
22 fied in paragraph (4)(A)(iii)) and are not less
23 than the first threshold lower limit of the risk
24 corridor (specified in paragraph (4)(A)(i)) for
25 the plan for the year, then no additional pay-

ments shall be made by the Administrator and no payments shall be made by (or collected from) the eligible entity offering the plan.

“(B) INCREASE IN PAYMENT IF ALLOWABLE COSTS ABOVE UPPER LIMIT OF RISK CORRIDOR.—

“(i) IN GENERAL.—If the allowable costs for the plan for the year are more than the first threshold upper limit of the risk corridor for the plan for the year, then the Administrator shall increase the total of the monthly payments made to the entity offering the plan for the year under subsection (a) by an amount equal to the sum of—

“(I) the applicable percent (as defined in subparagraph (D)) of such allowable costs which are more than such first threshold upper limit of the risk corridor and not more than the second threshold upper limit of the risk corridor for the plan for the year (as specified under paragraph (4)(A)(iv)); and

1 “(II) 90 percent of such allow-
 2 able costs which are more than such
 3 second threshold upper limit of the
 4 risk corridor.

5 “(ii) SPECIAL TRANSITIONAL COR-
 6 RIDOR FOR 2006 AND 2007.—If the Admin-
 7 istrator determines with respect to 2006 or
 8 2007 that at least 60 percent of Medicare
 9 Prescription Drug plans and
 10 MedicareAdvantage Plans (excluding MSA
 11 plans or private fee-for-service plans that
 12 do not provide qualified prescription drug
 13 coverage) have allowable costs for the plan
 14 for the year that are more than the first
 15 threshold upper limit of the risk corridor
 16 for the plan for the year and that such
 17 plans represent at least 60 percent of eligi-
 18 ble beneficiaries enrolled under this part,
 19 clause (i)(I) shall be applied by sub-
 20 stituting ‘90 percent’ for ‘applicable per-
 21 cent’.

22 “(C) PLAN PAYMENT IF ALLOWABLE
 23 COSTS BELOW LOWER LIMIT OF RISK COR-
 24 RIDOR.—If the allowable costs for the plan for
 25 the year are less than the first threshold lower

limit of the risk corridor for the plan for the year, then the entity offering the plan shall make a payment to the Administrator of an amount (or the Administrator shall otherwise recover from the plan an amount) equal to—

“(i) the applicable percent (as so defined) of such allowable costs which are less than such first threshold lower limit of the risk corridor and not less than the second threshold lower limit of the risk corridor for the plan for the year (as specified under paragraph (4)(A)(ii)); and

“(ii) 90 percent of such allowable costs which are less than such second threshold lower limit of the risk corridor.

“(D) APPLICABLE PERCENT DEFINED.—

For purposes of this paragraph, the term ‘applicable percent’ means—

“(i) for 2006 and 2007, 75 percent; and

“(ii) for 2008 and subsequent years, 50 percent.

“(3) ESTABLISHMENT OF ALLOWABLE COSTS.—For each year, the Administrator shall establish the allowable costs for each Medicare Pre-

1 scription Drug plan for the year. The allowable costs
 2 for a plan for a year shall be equal to the amount
 3 described in paragraph (1)(A)(i) for the plan for the
 4 year.

5 “(4) ESTABLISHMENT OF RISK CORRIDORS.—

6 “(A) IN GENERAL.—For each year (begin-
 7 ning with 2006), the Administrator shall estab-
 8 lish a risk corridor for each Medicare Prescrip-
 9 tion Drug plan. The risk corridor for a plan for
 10 a year shall be equal to a range as follows:

11 “(i) FIRST THRESHOLD LOWER
 12 LIMIT.—The first threshold lower limit of
 13 such corridor shall be equal to—

14 “(I) the target amount described
 15 in subparagraph (B) for the plan;
 16 minus

17 “(II) an amount equal to the
 18 first threshold risk percentage for the
 19 plan (as determined under subpara-
 20 graph (C)(i)) of such target amount.

21 “(ii) SECOND THRESHOLD LOWER
 22 LIMIT.—The second threshold lower limit
 23 of such corridor shall be equal to—

“(I) the target amount described
in subparagraph (B) for the plan;
minus

“(II) an amount equal to the sec-
ond threshold risk percentage for the
plan (as determined under subpara-
graph (C)(ii)) of such target amount.

“(iii) FIRST THRESHOLD UPPER
LIMIT.—The first threshold upper limit of
such corridor shall be equal to the sum
of—

“(I) such target amount; and

“(II) the amount described in
clause (i)(II).

“(iv) SECOND THRESHOLD UPPER
LIMIT.—The second threshold upper limit
of such corridor shall be equal to the sum
of—

“(I) such target amount; and

“(II) the amount described in
clause (ii)(II).

“(B) TARGET AMOUNT DESCRIBED.—The
target amount described in this paragraph is,
with respect to a Medicare Prescription Drug
plan offered by an eligible entity in a year—

1 “(i) in the case of a plan offered by
2 an eligible entity that provides standard
3 prescription drug coverage or actuarially
4 equivalent prescription drug coverage and
5 does not provide additional prescription
6 drug coverage pursuant to section 1860D–
7 6(a)(2), an amount equal to the total of
8 the monthly plan premiums paid to such
9 entity for such plan for the year pursuant
10 to subsection (a), reduced by the percent-
11 age specified in subparagraph (D); and

12 “(ii) in the case of a plan offered by
13 an eligible entity that provides additional
14 prescription drug coverage pursuant to sec-
15 tion 1860D–6(a)(2), an amount equal to
16 the total of the monthly plan premiums
17 paid to such entity for such plan for the
18 year pursuant to subsection (a) that are
19 related to standard prescription drug cov-
20 erage (determined using the rules under
21 section 1860D–14(b)), reduced by the per-
22 centage specified in subparagraph (D).

23 “(C) FIRST AND SECOND THRESHOLD

24 RISK PERCENTAGE DEFINED.—

1 “(i) FIRST THRESHOLD RISK PER-
2 CENTAGE.—Subject to clause (iii), for pur-
3 poses of this section, the first threshold
4 risk percentage is—

5 “(I) for 2006 and 2007, and 2.5
6 percent; ~~11-1108-1~~

7 “(II) for 2008 through 2011, 5
8 percent; and

9 ~~11-1108-1~~“(III) for 2012 and subsequent
10 years, a percentage established by the
11 Administrator, but in no case less
12 than 5 percent. ~~11-1108-1~~

13 “(ii) SECOND THRESHOLD RISK PER-
14 CENTAGE.—Subject to clause (iii), for pur-
15 poses of this section, the second threshold
16 risk percentage is—

17 ~~11-1108-1~~“(I) for 2006 and 2007, 5.0 per-
18 cent;

19 “(II) for 2008 through 2011, 10
20 percent ~~11-1108-1~~

21 “(III) for 2012 and subsequent
22 years, a percentage established by the
23 Administrator that is greater than the
24 percent established for the year under

1 clause (i)(III), but in no case less
2 than 10 percent.

3 “(iii) REDUCTION OF RISK PERCENT-
4 AGE TO ENSURE 2 PLANS IN AN AREA.—
5 Pursuant to paragraph (2) of section
6 1860D–13(d), the Administrator may re-
7 duce the applicable first or second thresh-
8 old risk percentage in an area in a year in
9 order to ensure the access to plans re-
10 quired under paragraph (1) of such sec-
11 tion.

12 “(D) TARGET AMOUNT NOT TO INCLUDE
13 ADMINISTRATIVE EXPENSES NEGOTIATED BE-
14 TWEEN THE ADMINISTRATOR AND THE ENTITY
15 OFFERING THE PLAN.—For each year (begin-
16 ning in 2006), the Administrator and the entity
17 offering a Medicare Prescription Drug plan
18 shall negotiate, as part of the negotiation proc-
19 ess described in section 1860D–13(b) during
20 the previous year, the percentage of the pay-
21 ments to the entity under subsection (a) with
22 respect to the plan that are attributable and
23 reasonably incurred for administrative expenses
24 for providing standard prescription drug cov-

erage or actuarially equivalent prescription drug coverage in the year. *relates*

“(5) PLANS AT RISK FOR ENTIRE AMOUNT OF ADDITIONAL PRESCRIPTION DRUG COVERAGE.—An eligible entity that offers a Medicare Prescription Drug plan that provides additional prescription drug coverage pursuant to section 1860D–6(a)(2) shall be at full financial risk for the provision of such additional coverage. *the entire risk assumption*

“(6) NO EFFECT ON ELIGIBLE BENEFICIARIES.—No change in payments made by reason of this subsection shall affect the beneficiary obligation under section 1860D–17 for the year in which such change in payments is made.

“(7) DISCLOSURE OF INFORMATION.—

“(A) IN GENERAL.—Each contract under this part shall provide that—

“(i) the entity offering a Medicare Prescription Drug plan shall provide the Administrator with such information as the Administrator determines is necessary to carry out this section; and *relates* §

“(ii) the Administrator shall have the right to inspect and audit any books and records of the eligible entity that pertain to

1 the information regarding costs provided to
2 the Administrator under paragraph (1).

3 “(B) RESTRICTION ON USE OF INFORMA-
4 TION.—Information disclosed or obtained pur-
5 suant to the provisions of this section may be
6 used by officers and employees of the Depart-
7 ment of Health and Human Services only for
8 the purposes of, and to the extent necessary in,
9 carrying out this section.

10 “(c) STABILIZATION RESERVE FUND.—

11 “(1) ESTABLISHMENT.—

12 “(A) IN GENERAL.—There is established,
13 within the Prescription Drug Account, a sta-
14 bilization reserve fund in which the Adminis-
15 trator shall deposit amounts on behalf of eligi-
16 ble entities in accordance with paragraph (2)
17 and such amounts shall be made available by
18 the Secretary for the use of eligible entities in
19 contract year 2008 and subsequent contract
20 years in accordance with paragraph (3).

21 “(B) REVERSION OF UNUSED AMOUNTS.—

22 Any amount in the stabilization reserve fund es-
23 tablished under subparagraph (A) that is not
24 expended by an eligible entity in accordance
25 with paragraph (3) or that was deposited for

the use of an eligible entity that no longer has a contract under this part shall revert for the use of the Prescription Drug Account.

“(2) DEPOSIT OF AMOUNTS FOR 5 YEARS.—

“(A) IN GENERAL.—If the target amount for a Medicare Prescription Drug plan for 2006, 2007, 2008, 2009, or 2010 (as determined under subsection (b)(4)(B)) exceeds the applicable costs for the plan for the year by more than 3 percent, then—

“(i) the entity offering the plan shall make a payment to the Administrator of an amount (or the Administrator shall otherwise recover from the plan an amount) equal to the portion of such excess that is in excess of 3 percent of the target amount; and

“(ii) the Administrator shall deposit an amount equal to the amount collected or otherwise recovered under clause (i) in the stabilization reserve fund on behalf of the eligible entity offering such plan.

“(B) APPLICABLE COSTS.—For purposes of subparagraph (A), the term ‘applicable costs’ means, with respect to a Medicare Prescription

1 Drug plan and year, an amount equal the sum
2 of—

3 “(i) the allowable costs for the plan
4 and year (as determined under subsection
5 (b)(3)(A); and

6 “(ii) the total amount by which
7 monthly payments to the plan were re-
8 duced (or otherwise recovered from the
9 plan) for the year under subsection
10 (b)(2)(C).

11 “(3) USE OF RESERVE FUND TO STABILIZE OR
12 REDUCE MONTHLY PLAN PREMIUMS.—

13 “(A) IN GENERAL.—For any contract year
14 beginning after 2007, an eligible entity offering
15 a Medicare Prescription Drug plan may use
16 funds in the stabilization reserve fund in the
17 Prescription Drug Account that were deposited
18 in such fund on behalf of the entity to stabilize
19 or reduce monthly plan premiums submitted
20 under section 1860D–12(b)(3). 00

21 “(B) PROCEDURES.—The Administrator
22 shall establish procedures for—

23 “(i) reducing monthly plan premiums
24 submitted under section 1860D–12(b)(3)
25 pursuant to subparagraph (A); and 122

“(ii) making payments from the plan stabilization reserve fund in the Prescription Drug Account to eligible entities that inform the Secretary under section 1860D-12(b)(5) of the entity’s intent to use funds in such reserve fund to reduce such premiums.

“(d) PORTION OF PAYMENTS OF MONTHLY PLAN PREMIUMS ATTRIBUTABLE TO ADMINISTRATIVE EXPENSES TIED TO PERFORMANCE REQUIREMENTS.—

“(1) IN GENERAL.—The Administrator shall establish procedures to adjust the portion of the payments made to an entity under subsection (a) that are attributable to administrative expenses (as determined pursuant to subsection (b)(4)(D)) to ensure that the entity meets the performance requirements described in clauses (ii) and (iii) of section 1860D-13(e)(4)(B).

“(2) NO EFFECT ON ELIGIBLE BENEFICIARIES.—No change in payments made by reason of this subsection shall affect the beneficiary obligation under section 1860D-17 for the year in which such change in payments is made.

“(e) PAYMENT TERMS.—

1 “(1) ADMINISTRATOR PAYMENTS.—Payments
 2 to an entity offering a Medicare Prescription Drug
 3 plan under this section shall be made in a manner
 4 determined by the Administrator and based upon the
 5 manner in which payments are made under section
 6 1853(a) (relating to payments to MedicareAdvantage
 7 organizations).

8 “(2) PLAN PAYMENTS.—The Administrator
 9 shall establish a process for collecting (or other oth-
 10 erwise recovering) amounts that an entity offering a
 11 Medicare Prescription Drug plan is required to make
 12 to the Administrator under this section.

13 “(f) PAYMENTS TO MEDICAREADVANTAGE PLANS.—
 14 For provisions related to payments to MedicareAdvantage
 15 organizations offering MedicareAdvantage plans for quali-
 16 fied prescription drug coverage made available under the
 17 plan, see section 1858A(c).

18 “(g) SECONDARY PAYER PROVISIONS.—The provi-
 19 sions of section 1862(b) shall apply to the benefits pro-
 20 vided under this part.

21 “COMPUTATION OF MONTHLY BENEFICIARY OBLIGATION

22 “SEC. 1860D-17. (a) BENEFICIARIES ENROLLED IN
 23 A MEDICARE PRESCRIPTION DRUG PLAN.—In the case of
 24 an eligible beneficiary enrolled under this part and in a
 25 Medicare Prescription Drug plan, the monthly beneficiary

1 obligation for enrollment in such plan in a year shall be
2 determined as follows:

3 “(1) MONTHLY PLAN PREMIUM EQUALS
4 MONTHLY NATIONAL AVERAGE PREMIUM.—If the
5 amount of the monthly plan premium approved by
6 the Administrator under section 1860D–13 for a
7 Medicare Prescription Drug plan for the year is
8 equal to the monthly national average premium (as
9 computed under section 1860D–15) for the area for
10 the year, the monthly beneficiary obligation of the
11 eligible beneficiary in that year shall be an amount
12 equal to the applicable percent (as determined in
13 subsection (c)) of the amount of such monthly na-
14 tional average premium.

15 “(2) MONTHLY PLAN PREMIUM LESS THAN
16 MONTHLY NATIONAL AVERAGE PREMIUM.—If the
17 amount of the monthly plan premium approved by
18 the Administrator under section 1860D–13 for the
19 Medicare Prescription Drug plan for the year is less
20 than the monthly national average premium (as
21 computed under section 1860D–15) for the area for
22 the year, the monthly beneficiary obligation of the
23 eligible beneficiary in that year shall be an amount
24 equal to—

1 “(A) the applicable percent of the amount
2 of such monthly national average premium;
3 minus

4 “(B) the amount by which such monthly
5 national average premium exceeds the amount
6 of the monthly plan premium approved by the
7 Administrator for the plan.

8 “(3) MONTHLY PLAN PREMIUM EXCEEDS
9 MONTHLY NATIONAL AVERAGE PREMIUM.—If the
10 amount of the monthly plan premium approved by
11 the Administrator under section 1860D–13 for a
12 Medicare Prescription Drug plan for the year ex-
13 ceeds the monthly national average premium (as
14 computed under section 1860D–15) for the area for
15 the year, the monthly beneficiary obligation of the
16 eligible beneficiary in that year shall be an amount
17 equal to the sum of—

18 “(A) the applicable percent of the amount
19 of such monthly national average premium; plus

20 “(B) the amount by which the monthly
21 plan premium approved by the Administrator
22 for the plan exceeds the amount of such month-
23 ly national average premium.

24 “(b) BENEFICIARIES ENROLLED IN A
25 MEDICARE ADVANTAGE PLAN.—In the case of an eligible

1 beneficiary that is enrolled in a MedicareAdvantage plan
 2 (except for an MSA plan or a private fee-for-service plan
 3 that does not provide qualified prescription drug cov-
 4 erage), the Medicare monthly beneficiary obligation for
 5 qualified prescription drug coverage shall be determined
 6 pursuant to section 1858A(d).

7 “(c) APPLICABLE PERCENT.—For purposes of this
 8 section, except as provided in section 1860D–19 (relating
 9 to premium subsidies for low-income individuals), the ap-
 10 plicable percent for any year is the percentage equal to
 11 a fraction—

12 “(1) the numerator of which is 30 percent; and

13 “(2) the denominator of which is 100 percent
 14 minus a percentage equal to—

15 “(A) the total reinsurance payments which
 16 the Administrator estimates will be made under
 17 section 1860D–20 to qualifying entities de-
 18 scribed in subsection (e)(3) of such section dur-
 19 ing the year; divided by

20 “(B) the sum of—

21 “(i) the amount estimated under sub-
 22 paragraph (A) for the year; and

23 “(ii) the total payments which the Ad-
 24 ministrator estimates will be made under
 25 sections 1860D–16 and 1858A(c) during

1 the year that relate to standard prescrip-
 2 tion drug coverage (or actuarially equiva-
 3 lent prescription drug coverage).

4 “COLLECTION OF MONTHLY BENEFICIARY OBLIGATION

5 “SEC. 1860D-18. (a) COLLECTION OF AMOUNT IN
 6 SAME MANNER AS PART B PREMIUM.—

7 “(1) IN GENERAL.—Subject to paragraph (2),
 8 the amount of the monthly beneficiary obligation
 9 (determined under section 1860D-17) applicable to
 10 an eligible beneficiary under this part (after applica-
 11 tion of any increase under section 1860D-
 12 2(b)(1)(A)) shall be collected and credited to the
 13 Prescription Drug Account in the same manner as
 14 the monthly premium determined under section
 15 1839 is collected and credited to the Federal Supple-
 16 mentary Medical Insurance Trust Fund under sec-
 17 tion 1840.

18 “(2) PROCEDURES FOR SPONSOR TO PAY OBLI-
 19 GATION ON BEHALF OF RETIREE.—The Adminis-
 20 trator shall establish procedures under which an eli-
 21 gible beneficiary enrolled in a Medicare Prescription
 22 Drug plan may elect to have the sponsor (as defined
 23 in paragraph (5) of section 1860D-20(e)) of employ-
 24 ment-based retiree health coverage (as defined in
 25 paragraph (4)(B) of such section) in which the bene-
 26 ficiary is enrolled pay the amount of the monthly

beneficiary obligation applicable to the beneficiary under this part directly to the Administrator.

“(b) INFORMATION NECESSARY FOR COLLECTION.—

In order to carry out subsection (a), the Administrator shall transmit to the Commissioner of Social Security—

“(1) by the beginning of each year, the name, social security account number, monthly beneficiary obligation owed by each individual enrolled in a Medicare Prescription Drug plan for each month during the year, and other information determined appropriate by the Administrator; and

“(2) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.

“(c) COLLECTION FOR BENEFICIARIES ENROLLED IN A MEDICAREADVANTAGE PLAN.—For provisions related to the collection of the monthly beneficiary obligation for qualified prescription drug coverage under a MedicareAdvantage plan, see section 1858A(e).

“PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

“SEC. 1860D-19. (a) AMOUNT OF SUBSIDIES.—

“(1) FULL PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR QUALIFIED MEDICARE BENEFICIARIES.—In the case of a qualified medicare beneficiary (as defined in paragraph (4)(A))—

1 “(A) section 1860D-17 shall be applied—

2 “(i) in subsection (c), by substituting
3 ‘0 percent’ for the applicable percent that
4 would otherwise apply under such sub-
5 section; and

6 “(ii) in subsection (a)(3)(B), by sub-
7 stituting ‘the amount of the monthly plan
8 premium for the Medicare Prescription
9 Drug plan with the lowest monthly plan
10 premium in the area that the beneficiary
11 resides’ for ‘the amount of such monthly
12 national average premium’, but only if
13 there is no Medicare Prescription Drug
14 plan offered in the area in which the indi-
15 vidual resides that has a monthly plan pre-
16 mium for the year that is equal to or less
17 than the monthly national average pre-
18 mium (as computed under section 1860D-
19 15) for the area for the year;

20 “(B) the annual deductible applicable
21 under section 1860D-6(c)(1) in a year shall be
22 reduced to \$0;

23 “(C) section 1860D-6(c)(2) shall be ap-
24 plied by substituting ‘2.5 percent’ for ‘50 per-
25 cent’ each place it appears;

“(D) such individual shall be responsible for cost-sharing for the cost of any covered drug provided in the year (after the individual has reached the initial coverage limit described in section 1860D-6(c)(3) and before the individual has reached the annual out-of-pocket limit under section 1860D-6(c)(4)(A)), that is equal to 5.0 percent; and

“(E) section 1860D-6(c)(4)(A) shall be applied by substituting ‘2.5 percent’ for ‘10 percent’.

In no case may the application of subparagraph (A) result in a monthly beneficiary obligation that is below 0.

“(2) FULL PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR SPECIFIED LOW INCOME MEDICARE BENEFICIARIES AND QUALIFYING INDIVIDUALS.—In the case of a specified low income medicare beneficiary (as defined in paragraph (4)(B)) or a qualifying individual (as defined in paragraph (4)(C))—

“(A) section 1860D-17 shall be applied—

“(i) in subsection (c), by substituting ‘0 percent’ for the applicable percent that

1 would otherwise apply under such sub-
2 section; and

3 “(ii) in subsection (a)(3)(B), by sub-
4 stituting ‘the amount of the monthly plan
5 premium for the Medicare Prescription
6 Drug plan with the lowest monthly plan
7 premium in the area that the beneficiary
8 resides’ for ‘the amount of such monthly
9 national average premium’, but only if
10 there is no Medicare Prescription Drug
11 plan offered in the area in which the indi-
12 vidual resides that has a monthly plan pre-
13 mium for the year that is equal to or less
14 than the monthly national average pre-
15 mium (as computed under section 1860D-
16 15) for the area for the year;

17 “(B) the annual deductible applicable
18 under section 1860D-6(c)(1) in a year shall be
19 reduced to \$0;

20 “(C) section 1860D-6(c)(2) shall be ap-
21 plied by substituting ‘5.0 percent’ for ‘50 per-
22 cent’ each place it appears;

23 “(D) such individual shall be responsible
24 for cost-sharing for the cost of any covered
25 drug provided in the year (after the individual

has reached the initial coverage limit described in section 1860D-6(c)(3) and before the individual has reached the annual out-of-pocket limit under section 1860D-6(c)(4)(A)), that is equal to 10.0 percent; and

“(E) section 1860D-6(c)(4)(A) shall be applied by substituting ‘2.5 percent’ for ‘10 percent’.

In no case may the application of subparagraph (A) result in a monthly beneficiary obligation that is below 0.

“(3) SLIDING SCALE PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR SUBSIDY-ELIGIBLE INDIVIDUALS.—

“(A) IN GENERAL.—In the case of a subsidy-eligible individual (as defined in paragraph (4)(D))—

“(i) section 1860D-17 shall be applied—

“(I) in subsection (c), by substituting ‘subsidy percent’ for the applicable percentage that would otherwise apply under such subsection; and

“(II) in subparagraphs (A) and (B) of subsection (a)(3), by sub-

1 stituting ‘the amount of the monthly
 2 plan premium for the Medicare Pre-
 3 scription Drug plan with the lowest
 4 monthly plan premium in the area
 5 that the beneficiary resides’ for ‘the
 6 amount of such monthly national av-
 7 erage premium’, but only if there is
 8 no Medicare Prescription Drug plan
 9 offered in the area in which the indi-
 10 vidual resides that has a monthly plan
 11 premium for the year that is equal to
 12 or less than the monthly national av-
 13 erage premium (as computed under
 14 section 1860D-15) for the area for
 15 the year; and

16 “(ii) the annual deductible applicable
 17 under section 1860D-6(c)(1)—

18 “(I) for 2006, shall be reduced to
 19 \$50; and

20 “(II) for a subsequent year, shall
 21 be reduced to the amount specified
 22 under this clause for the previous year
 23 increased by the percentage specified
 24 in section 1860D-6(c)(5) for the year
 25 involved;

“(iii) section 1860D-6(c)(2) shall be applied by substituting ‘10.0 percent’ for ‘50 percent’ each place it appears;

“(iv) such individual shall be responsible for cost-sharing for the cost of any covered drug provided in the year (after the individual has reached the initial coverage limit described in section 1860D-6(c)(3) and before the individual has reached the annual out-of-pocket limit under section 1860D-6(c)(4)(A)), that is equal to 20.0 percent; and

“(v) such individual shall be responsible for the cost-sharing described in section 1860D-6(c)(4)(A).

In no case may the application of clause (i) result in a monthly beneficiary obligation that is below 0.

“(B) SUBSIDY PERCENT DEFINED.—For purposes of subparagraph (A)(i), the term ‘subsidy percent’ means, with respect to a State, a percent determined on a linear sliding scale ranging from—

“(i) 0 percent with respect to a subsidy-eligible individual residing in the State

1 whose income does not exceed 135 percent
2 of the poverty line; to

3 “(ii) the highest percentage that
4 would otherwise apply under section
5 1860D-17 in the service area in which the
6 subsidy-eligible individual resides, in the
7 case of a subsidy-eligible individual resid-
8 ing in the State whose income equals 160
9 percent of the poverty line.

10 “(4) DEFINITIONS.—In this part:

11 “(A) QUALIFIED MEDICARE BENE-
12 FICIARY.—Subject to subparagraph (H), the
13 term ‘qualified medicare beneficiary’ means an
14 individual who—

15 “(i) is enrolled under this part, in-
16 cluding an individual who is enrolled under
17 a MedicareAdvantage plan;

18 “(ii) is eligible for medicare cost-shar-
19 ing described in section 1905(p)(3) under
20 the State plan under title XIX (or under
21 a waiver of such plan), on the basis of
22 being described in section 1905(p)(1), as
23 determined under such plan (or under a
24 waiver of plan); and

25 “(iii) is not—

“(I) a specified low-income medicare beneficiary;

“(II) a qualifying individual; or

“(III) a dual eligible individual.

“(B) SPECIFIED LOW INCOME MEDICARE BENEFICIARY.—Subject to subparagraph (H), the term ‘specified low income medicare beneficiary’ means an individual who—

“(i) is enrolled under this part, including an individual who is enrolled under a MedicareAdvantage plan;

“(ii) is eligible for medicare cost-sharing described in section 1905(p)(3)(A)(ii) under the State plan under title XIX (or under a waiver of such plan), on the basis of being described in section 1902(a)(10)(E)(iii), as determined under such plan (or under a waiver of plan); and

“(iii) is not—

“(I) a qualified medicare beneficiary;

“(II) a qualifying individual; or

“(III) a dual eligible individual.

1 “(C) QUALIFYING INDIVIDUAL.—Subject
2 to subparagraph (H), the term ‘qualifying indi-
3 vidual’ means an individual who—

4 “(i) is enrolled under this part, in-
5 cluding an individual who is enrolled under
6 a Medicare Advantage plan;

7 “(ii) is eligible for medicare cost-shar-
8 ing described in section 1905(p)(3)(A)(ii)
9 under the State plan under title XIX (or
10 under a waiver of such plan), on the basis
11 of being described in section
12 1902(a)(10)(E)(iv) (without regard to any
13 termination of the application of such sec-
14 tion under title XIX), as determined under
15 such plan (or under a waiver of such plan);
16 and

17 “(iii) is not—

18 “(I) a qualified medicare bene-
19 ficiary;

20 “(II) a specified low-income
21 medicare beneficiary; or

22 “(III) a dual eligible individual.

23 “(D) SUBSIDY-ELIGIBLE INDIVIDUAL.—
24 Subject to subparagraph (H), the term ‘sub-
25 sidy-eligible individual’ means an individual—

“(i) who is enrolled under this part,
including an individual who is enrolled
under a Medicare Advantage plan;

“(ii) whose income is less than 160
percent of the poverty line; and

“(iii) who is not—

“(I) a qualified medicare bene-
ficiary;

“(II) a specified low-income
medicare beneficiary;

“(III) a qualifying individual; or

“(IV) a dual eligible individual.

“(E) DUAL ELIGIBLE INDIVIDUAL.—

“(i) IN GENERAL.—The term ‘dual el-
igible individual’ means an individual who
is—

“(I) enrolled under title XIX or
under a waiver under section 1115 of
the requirements of such title for
medical assistance that is not less
than the medical assistance provided
to an individual described in section
1902(a)(10)(A)(i) and includes cov-
ered outpatient drugs (as such term is

1 defined for purposes of section 1927);
2 and

3 “(II) entitled to benefits under
4 part A and enrolled under part B.

5 “(ii) INCLUSION OF MEDICALLY
6 NEEDY.—Such term includes an individual
7 described in section 1902(a)(10)(C).

8 “(F) POVERTY LINE.—The term ‘poverty
9 line’ has the meaning given such term in sec-
10 tion 673(2) of the Community Services Block
11 Grant Act (42 U.S.C. 9902(2)), including any
12 revision required by such section.

13 “(G) ELIGIBILITY DETERMINATIONS.—Be-
14 ginning on November 1, 2005, the determina-
15 tion of whether an individual residing in a State
16 is an individual described in subparagraph (A),
17 (B), (C), (D), or (E) and, for purposes of para-
18 graph (3), the amount of an individual’s in-
19 come, shall be determined under the State med-
20 icaid plan for the State under section 1935(a).
21 In the case of a State that does not operate
22 such a medicaid plan (either under title XIX or
23 under a statewide waiver granted under section
24 1115), such determination shall be made under
25 arrangements made by the Administrator.

1 “(H) NONAPPLICATION TO DUAL ELIGIBLE
2 INDIVIDUALS AND TERRITORIAL RESIDENTS.—

3 In the case of an individual who is a dual eligi-
4 ble individual or an individual who is not a resi-
5 dent of the 50 States or the District of Colum-
6 bia—

7 “(i) the subsidies provided under this
8 section shall not apply; and

9 “(ii) in the case of such an individual
10 who is not a resident of the 50 States or
11 the District of Columbia, such individual
12 may be provided with medical assistance
13 for covered outpatient drugs (as such term
14 is defined for purposes of section 1927) in
15 accordance with section 1935 under the
16 State medicaid program under title XIX.

17 “(I) UPDATE OF ASSET OR RESOURCE
18 TEST.—With respect to eligibility determina-
19 tions for premium and cost-sharing subsidies
20 under this section that are made on or after
21 January 1, 2009, such determinations shall be
22 made (to the extent a State, as of such date,
23 has not already eliminated the application of an
24 asset or resource test under section

1 1905(p)(1)(C)) in accordance with the fol-
2 lowing:

3 “(i) SELF-DECLARATION OF VALUE.—

4 “(I) IN GENERAL.—A State shall
5 permit an individual applying for such
6 subsidies to declare and certify by sig-
7 nature under penalty of perjury on
8 the application form that the value of
9 the individual’s assets or resources (or
10 the combined value of the individual’s
11 assets or resources and the assets or
12 resources of the individual’s spouse),
13 as determined under section 1613 for
14 purposes of the supplemental security
15 income program, does not exceed
16 \$10,000 (\$20,000 in the case of the
17 combined value of the individual’s as-
18 sets or resources and the assets or re-
19 sources of the individual’s spouse).

20 “(II) ANNUAL ADJUSTMENT.—

21 Beginning on January 1, 2010, and
22 for each subsequent year, the dollar
23 amounts specified in subclause (I) for
24 the preceding year shall be increased
25 by the percentage increase in the Con-

sumer Price Index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.

“(ii) METHODOLOGY FLEXIBILITY.—

Nothing in clause (i) shall be construed as prohibiting a State in making eligibility determinations for premium and cost-sharing subsidies under this section from using asset or resource methodologies that are less restrictive than the methodologies used under 1613 for purposes of the supplemental security income program.

“(J) DEVELOPMENT OF MODEL DECLARATION FORM.—The Secretary shall—

“(i) develop a model, simplified application form for individuals to use in making a self-declaration of assets or resources in accordance with subparagraph (I)(i); and

“(ii) provide such form to States and, for purposes of outreach under section 1144, the Commissioner of Social Security.”.

1 “(b) RULES IN APPLYING COST-SHARING SUB-
 2 SIDIES.—Nothing in this section shall be construed as pre-
 3 venting an eligible entity offering a Medicare Prescription
 4 Drug plan or a MedicareAdvantage organization offering
 5 a MedicareAdvantage plan from waiving or reducing the
 6 amount of the deductible or other cost-sharing otherwise
 7 applicable pursuant to section 1860D–6(a)(2).

8 “(c) ADMINISTRATION OF SUBSIDY PROGRAM.—The
 9 Administrator shall establish a process whereby, in the
 10 case of an individual eligible for a cost-sharing subsidy
 11 under subsection (a) who is enrolled in a Medicare Pre-
 12 scription Drug plan or a MedicareAdvantage plan—

13 “(1) the Administrator provides for a notifica-
 14 tion of the eligible entity or MedicareAdvantage or-
 15 ganization involved that the individual is eligible for
 16 a cost-sharing subsidy and the amount of the sub-
 17 sidy under such subsection;

18 “(2) the entity or organization involved reduces
 19 the cost-sharing otherwise imposed by the amount of
 20 the applicable subsidy and submits to the Adminis-
 21 trator information on the amount of such reduction;
 22 and

23 “(3) the Administrator periodically and on a
 24 timely basis reimburses the entity or organization
 25 for the amount of such reductions.

1 The reimbursement under paragraph (3) may be com-
 2 puted on a capitated basis, taking into account the actu-
 3 arial value of the subsidies and with appropriate adjust-
 4 ments to reflect differences in the risks actually involved.

5 “(d) RELATION TO MEDICAID PROGRAM.—For provi-
 6 sions providing for eligibility determinations and addi-
 7 tional Federal payments for expenditures related to pro-
 8 viding prescription drug coverage for dual eligible individ-
 9 uals and territorial residents under the medicaid program,
 10 see section 1935.

11 “REINSURANCE PAYMENTS FOR EXPENSES INCURRED IN
 12 PROVIDING PRESCRIPTION DRUG COVERAGE ABOVE
 13 THE ANNUAL OUT-OF-POCKET THRESHOLD

14 “SEC. 1860D–20. (a) REINSURANCE PAYMENTS.—

15 “(1) IN GENERAL.—Subject to section 1860D–
 16 21(b), the Administrator shall provide in accordance
 17 with this section for payment to a qualifying entity
 18 of the reinsurance payment amount (as specified in
 19 subsection (c)(1)) for costs incurred by the entity in
 20 providing prescription drug coverage for a qualifying
 21 covered individual after the individual has reached
 22 the annual out-of-pocket threshold specified in sec-
 23 tion 1860D–6(c)(4)(B) for the year.

24 “(2) BUDGET AUTHORITY.—This section con-
 25 stitutes budget authority in advance of appropria-
 26 tions Acts and represents the obligation of the Ad-

1 administrator to provide for the payment of amounts
2 provided under this section.

3 “(b) NOTIFICATION OF SPENDING UNDER THE PLAN
4 FOR COSTS INCURRED IN PROVIDING PRESCRIPTION
5 DRUG COVERAGE ABOVE THE ANNUAL OUT-OF-POCKET
6 THRESHOLD.—

7 “(1) IN GENERAL.—Each qualifying entity shall
8 notify the Administrator of the following with re-
9 spect to a qualifying covered individual for a cov-
10 erage year:

11 “(A) TOTAL ACTUAL COSTS.—The total
12 amount (if any) of costs that the qualifying en-
13 tity incurred in providing prescription drug cov-
14 erage for the individual in the year after the in-
15 dividual had reached the annual out-of-pocket
16 threshold specified in section 1860D–6(c)(4)(B)
17 for the year.

18 “(B) AMOUNTS RESULTING IN ACTUAL
19 COSTS.—With respect to the total amount
20 under subparagraph (A) for the year—

21 “(i) the aggregate amount of pay-
22 ments made by the entity to pharmacies
23 and other entities with respect to such cov-
24 erage for such enrollees; and

“(ii) the aggregate amount of discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made to the entity with respect to such coverage for such enrollees.

“(2) CERTAIN EXPENSES NOT INCLUDED.—The amount under paragraph (1)(A) may not include—

“(A) administrative expenses incurred in providing the coverage described in paragraph (1)(A);

“(B) amounts expended on providing additional prescription drug coverage pursuant to section 1860D–6(a)(2); or

“(C) discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made to the entity with respect to coverage described in paragraph (1)(A).

“(3) RESTRICTION ON USE OF INFORMATION.—The restriction specified in section 1860D–16(b)(7)(B) shall apply to information disclosed or obtained pursuant to the provisions of this section.

“(c) REINSURANCE PAYMENT AMOUNT.—

“(1) IN GENERAL.—The reinsurance payment amount under this subsection for a qualifying cov-

1 ered individual for a coverage year is an amount
2 equal to 80 percent (or 65 percent with respect to
3 a qualifying covered individual described in sub-
4 section (e)(2)(D)) of the allowable costs (as specified
5 in paragraph (2)) incurred by the qualifying entity
6 with respect to the individual and year.

7 “(2) ESTABLISHMENT OF ALLOWABLE
8 COSTS.—In the case of a qualifying entity that has
9 incurred costs described in subsection (b)(1)(A) with
10 respect to a qualifying covered individual for a cov-
11 erage year, the Administrator shall establish the al-
12 lowable costs for the individual and year. Such al-
13 lowable costs shall be equal to the amount described
14 in such subsection for the individual and year.

15 “(d) PAYMENT METHODS.—

16 “(1) IN GENERAL.—Payments under this sec-
17 tion shall be based on such a method as the Admin-
18 istrator determines. The Administrator may estab-
19 lish a payment method by which interim payments
20 of amounts under this section are made during a
21 year based on the Administrator’s best estimate of
22 amounts that will be payable after obtaining all of
23 the information.

1 “(2) SOURCE OF PAYMENTS.—Payments under
2 this section shall be made from the Prescription
3 Drug Account.

4 “(e) DEFINITIONS.—In this section:

5 “(1) COVERAGE YEAR.—The term ‘coverage
6 year’ means a calendar year in which covered drugs
7 are dispensed if a claim for payment is made under
8 the plan for such drugs, regardless of when the
9 claim is paid.

10 “(2) QUALIFYING COVERED INDIVIDUAL.—The
11 term ‘qualifying covered individual’ means an indi-
12 vidual who—

13 “(A) is enrolled in this part and in a Medi-
14 care Prescription Drug plan;

15 “(B) is enrolled in this part and in a
16 MedicareAdvantage plan (except for an MSA
17 plan or a private fee-for-service plan that does
18 not provide qualified prescription drug cov-
19 erage);

20 “(C) is eligible for, but not enrolled in, the
21 program under this part, and is covered under
22 a qualified retiree prescription drug plan; or

23 “(D) is eligible for, but not enrolled in, the
24 program under this part, and is covered under

1 a qualified State pharmaceutical assistance pro-
2 gram.

3 “(3) QUALIFYING ENTITY.—The term ‘quali-
4 fying entity’ means any of the following that has en-
5 tered into an agreement with the Administrator to
6 provide the Administrator with such information as
7 may be required to carry out this section:

8 “(A) An eligible entity offering a Medicare
9 Prescription Drug plan under this part.

10 “(B) A MedicareAdvantage organization
11 offering a MedicareAdvantage plan under part
12 C (except for an MSA plan or a private fee-for-
13 service plan that does not provide qualified pre-
14 scription drug coverage).

15 “(C) The sponsor of a qualified retiree pre-
16 scription drug plan.

17 “(D) A State offering a qualified State
18 pharmaceutical assistance program.

19 “(4) QUALIFIED RETIREE PRESCRIPTION DRUG
20 PLAN.—

21 “(A) IN GENERAL.—The term ‘qualified
22 retiree prescription drug plan’ means employ-
23 ment-based retiree health coverage if, with re-
24 spect to a qualifying covered individual who is

covered under the plan, the following requirements are met:

“(i) ATTESTATION OF ACTUARIAL VALUE OF COVERAGE.—The sponsor of the plan shall, annually or at such other time as the Administrator may require, provide the Administrator an attestation, in accordance with the procedures established under section 1860D-6(f), that the actuarial value of prescription drug coverage under the plan is at least equal to the actuarial value of standard prescription drug coverage.

“(ii) AUDITS.—The sponsor of the plan, or an administrator of the plan designated by the sponsor, shall maintain (and afford the Administrator access to) such records as the Administrator may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage and the accuracy of payments made under this part to and by the plan.

“(B) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term ‘employment-

1 based retiree health coverage' means health in-
 2 surance or other coverage, whether provided by
 3 voluntary insurance coverage or pursuant to
 4 statutory or contractual obligation, of health
 5 care costs for retired individuals (or for such in-
 6 dividuals and their spouses and dependents)
 7 based on their status as former employees or
 8 labor union members.

9 “(5) QUALIFIED STATE PHARMACEUTICAL AS-
 10 SISTANCE PROGRAM.—

11 “(A) IN GENERAL.—The term ‘qualified
 12 State pharmaceutical assistance program’
 13 means a State pharmaceutical assistance pro-
 14 gram if, with respect to a qualifying covered in-
 15 dividual who is covered under the program, the
 16 following requirements are met:

17 “(i) ASSURANCE.—The State offering
 18 the program shall, annually or at such
 19 other times as the Administrator may re-
 20 quire, provide the Administrator an attes-
 21 tation that, in accordance with the proce-
 22 dures established under section 1860D-
 23 6(f), that—

24 “(I) the actuarial value of pre-
 25 scription drug coverage under the pro-

gram is at least equal to the actuarial value of standard prescription drug coverage; and

“(II) the actuarial value of subsidies to individuals provided under the program are at least equal to the actuarial value of the subsidies that would apply under section 1860D–19 if the individual was enrolled under this part rather than under the program.

“(ii) DISCLOSURE OF INFORMATION.—The State complies with the requirements described in clauses (i) and (ii) of section 1860D–16(b)(7)(A).

“(B) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—For purposes of subparagraph (A), the term ‘State pharmaceutical assistance program’ means a program—

“(i) that is in operation as of the date of enactment of the Prescription Drug and Medicare Improvement Act of 2003;

“(ii) that is sponsored and financed by a State; and

1 “(iii) that provides coverage for out-
 2 patient drugs for individuals in the State
 3 who meet income- and resource-related
 4 qualifications specified under such pro-
 5 gram.

6 “(6) SPONSOR.—The term ‘sponsor’ means a
 7 plan sponsor, as defined in section 3(16)(B) of the
 8 Employee Retirement Income Security Act of 1974.

9 “(f) DISTRIBUTION OF REINSURANCE PAYMENT
 10 AMOUNTS.—

11 “(1) IN GENERAL.—Any sponsor meeting the
 12 requirements of subsection (e)(3) with respect to a
 13 quarter in a calendar year, but which is not an em-
 14 ployer, shall distribute the reinsurance payments re-
 15 ceived for such quarter under subsection (c) to the
 16 employers contributing to the qualified retiree pre-
 17 scription drug plan maintained by such sponsor dur-
 18 ing that quarter, in the manner described in para-
 19 graphs (2) and (3).

20 “(2) ALLOCATION.—The reinsurance payments
 21 to be distributed pursuant to paragraph (1) shall be
 22 allocated proportionally among all employers who
 23 contribute to the plan during the quarter with re-
 24 spect to which the payments are received. The share
 25 allocated to each employer contributing to the plan

during a quarter shall be determined by multiplying the total reinsurance payments received by the sponsor for the quarter by a fraction, the numerator of which is the total contributions made by an employer for that quarter, and the denominator of which is the total contributions required to be made to the plan by all employers for that quarter. Any share allocated to an employer required to contribute for a quarter who does not make the contributions required for that quarter on or before the date due shall be retained by the sponsor for the benefit of the plan as a whole.

“(3) TIMING.—Reinsurance payments required to be distributed to employers pursuant to this subsection shall be distributed as soon as practicable after received by the sponsor, but in no event later than the end of the quarter immediately following the quarter in which such reinsurance payments are received by the sponsor.

“(4) REGULATIONS.—The Secretary shall promulgate regulations providing that any sponsor subject to the requirements of this subsection who fails to meet such requirements shall not be eligible for a payment under this section.

1 "DIRECT SUBSIDY FOR SPONSOR OF A QUALIFIED RE-
2 TIREE PRESCRIPTION DRUG PLAN FOR PLAN EN-
3 ROLLEES ELIGIBLE FOR, BUT NOT ENROLLED IN,
4 THIS PART

5 "SEC. 1860D-21. (a) DIRECT SUBSIDY.—

6 "(1) IN GENERAL.—The Administrator shall
7 provide for the payment to a sponsor of a qualified
8 retiree prescription drug plan (as defined in section
9 1860D-20(e)(4)) for each qualifying covered indi-
10 vidual (described in subparagraph (C) of section
11 1860D-20(e)(2)) enrolled in the plan for each
12 month for which such individual is so enrolled.

13 "(2) AMOUNT OF PAYMENT.—

14 "(A) IN GENERAL.—The amount of the
15 payment under paragraph (1) shall be an
16 amount equal to the direct subsidy percent de-
17 termined for the year of the monthly national
18 average premium for the area for the year (de-
19 termined under section 1860D-15), as adjusted
20 using the risk adjusters that apply to the stand-
21 ard prescription drug coverage published under
22 section 1860D-11.

23 "(B) DIRECT SUBSIDY PERCENT.—For
24 purposes of subparagraph (A), the term 'direct

subsidy percent' means the percentage equal

to—

“(i) 100 percent; minus

“(ii) the applicable percent for the
year (as determined under section 1860D—

17(c).

“(b) PAYMENT METHODS.—

“(1) IN GENERAL.—Payments under this section shall be based on such a method as the Administrator determines. The Administrator may establish a payment method by which interim payments of amounts under this section are made during a year based on the Administrator's best estimate of amounts that will be payable after obtaining all of the information.

“(2) SOURCE OF PAYMENTS.—Payments under this section shall be made from the Prescription Drug Account.

“DIRECT SUBSIDIES FOR QUALIFIED STATE OFFERING A STATE PHARMACEUTICAL ASSISTANCE PROGRAM FOR PROGRAM ENROLLEES ELIGIBLE FOR, BUT NOT ENROLLED IN, THIS PART

“SEC. 1860D-22. (a) DIRECT SUBSIDY.—

“(1) IN GENERAL.—The Administrator shall provide for the payment to a State offering a qualified State pharmaceutical assistance program (as de-

1 fined in section 1860D-20(e)(6)) for each qualifying
2 covered individual (described in subparagraph (D) of
3 section 1860D-(e)(2)) enrolled in the program for
4 each month for which such individual is so enrolled.

5 “(2) AMOUNT OF PAYMENT.—

6 “(A) IN GENERAL.—The amount of the
7 payment under paragraph (1) shall be an
8 amount equal to the amount of payment for the
9 area and year made under section 1860D-
10 21(a)(2).

11 “(b) ADDITIONAL SUBSIDY.—

12 “(1) IN GENERAL.—The Administrator shall
13 provide for the payment to a State offering a quali-
14 fied State pharmaceutical program (as defined in
15 section 1860D-20(e)(6)) for each applicable low-in-
16 come individual enrolled in the program for each
17 month for which such individual is so enrolled.

18 “(2) AMOUNT OF PAYMENT.—

19 “(A) IN GENERAL.—The amount of the
20 payment under paragraph (1) shall be the
21 amount the Administrator estimates would have
22 been made to an entity or organization under
23 section 1860D-19 with respect to the applicable
24 low-income individual if such individual was en-
25 rolled in this part and under a Medicare Pre-

scription Drug plan or a Medicare Advantage plan.

“(B) MAXIMUM PAYMENTS.—In no case may the amount of the payment determined under subparagraph (A) with respect to an applicable low-income individual exceed, as estimated by the Administrator, the average amounts made in a year under section 1860D–19 on behalf of an eligible beneficiary enrolled under this part with income that is the same as the income of the applicable low-income individual.

“(3) APPLICABLE LOW-INCOME INDIVIDUAL.—

For purposes of this subsection, the term ‘applicable low-income individual’ means an individual who is both—

“(A) a qualifying covered individual (described in subparagraph (D) of section 1860D–(e)(2)); and

“(B) a qualified medicare beneficiary, a specified low income medicare beneficiary, or a subsidy-eligible individual, as such terms are defined in section 1860D–19(a)(4).

“(c) PAYMENT METHODS.—

1 “(1) IN GENERAL.—Payments under this sec-
 2 tion shall be based on such a method as the Admin-
 3 istrator determines. The Administrator may estab-
 4 lish a payment method by which interim payments
 5 of amounts under this section are made during a
 6 year based on the Administrator’s best estimate of
 7 amounts that will be payable after obtaining all of
 8 the information.

9 “(2) SOURCE OF PAYMENTS.—Payments under
 10 this section shall be made from the Prescription
 11 Drug Account.

12 “(d) CONSTRUCTION.—Nothing in this section or sec-
 13 tion 1860D–20 shall effect the provisions of section
 14 1860D–26(b).

15 “Subpart 3—Miscellaneous Provisions

16 “PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL 17 SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

18 “SEC. 1860D–25. (a) ESTABLISHMENT.—

19 “(1) IN GENERAL.—There is created within the
 20 Federal Supplementary Medical Insurance Trust
 21 Fund established by section 1841 an account to be
 22 known as the ‘Prescription Drug Account’ (in this
 23 section referred to as the ‘Account’).

24 “(2) FUNDS.—The Account shall consist of
 25 such gifts and bequests as may be made as provided

1 in section 201(i)(1), and such amounts as may be
 2 deposited in, or appropriated to, the Account as pro-
 3 vided in this part.

4 “(3) SEPARATE FROM REST OF TRUST FUND.—

5 Funds provided under this part to the Account shall
 6 be kept separate from all other funds within the
 7 Federal Supplementary Medical Insurance Trust
 8 Fund.

9 “(b) PAYMENTS FROM ACCOUNT.—

10 “(1) IN GENERAL.—The Managing Trustee
 11 shall pay from time to time from the Account such
 12 amounts as the Secretary certifies are necessary to
 13 make payments to operate the program under this
 14 part, including—

15 “(A) payments to eligible entities under
 16 section 1860D–16;

17 “(B) payments under 1860D–19 for low-
 18 income subsidy payments for cost-sharing;

19 “(C) reinsurance payments under section
 20 1860D–20;

21 “(D) payments to sponsors of qualified re-
 22 tiree prescription drug plans under section
 23 1860D–21;

24 “(E) payments to MedicareAdvantage or-
 25 ganizations for the provision of qualified pre-

1 scription drug coverage under section 1858A(c);
2 and

3 “(F) payments with respect to administra-
4 tive expenses under this part in accordance with
5 section 201(g).”

6 “(2) TREATMENT IN RELATION TO PART B PRE-
7 MIUM.—Amounts payable from the Account shall not
8 be taken into account in computing actuarial rates
9 or premium amounts under section 1839.

“(c) APPROPRIATIONS TO COVER BENEFITS AND ADMINISTRATIVE COSTS.—There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the payments and transfers made from the Account in the year.

16 "OTHER RELATED PROVISIONS

17 “SEC. 1860D-26. (a) RESTRICTION ON ENROLL-
18 MENT IN A MEDICARE PRESCRIPTION DRUG PLAN OF-
19 FERED BY A SPONSOR OF EMPLOYMENT-BASED RETIREE
20 HEALTH COVERAGE.—

“(1) IN GENERAL.—In the case of a Medicare Prescription Drug plan offered by an eligible entity that is a sponsor (as defined in paragraph (5) of section 1860D–20(e)) of employment-based retiree health coverage (as defined in paragraph (4)(B) of such section), notwithstanding any other provision of

1 this part and in accordance with regulations of the
 2 Administrator, the entity offering the plan may re-
 3 strict the enrollment of eligible beneficiaries enrolled
 4 under this part to eligible beneficiaries who are en-
 5 rolled in such coverage.

6 “(2) LIMITATION.—The sponsor of the employ-
 7 ment-based retiree health coverage described in
 8 paragraph (1) may not offer enrollment in the Medi-
 9 care Prescription Drug plan described in such para-
 10 graph based on the health status of eligible bene-
 11 ficiaries enrolled for such coverage.

12 “(b) COORDINATION WITH STATE PHARMACEUTICAL
 13 ASSISTANCE PROGRAMS.—

14 “(1) IN GENERAL.—An eligible entity offering a
 15 Medicare Prescription Drug plan, or a
 16 MedicareAdvantage organization offering a
 17 MedicareAdvantage plan (other than an MSA plan
 18 or a private fee-for-service plan that does not pro-
 19 vide qualified prescription drug coverage), may enter
 20 into an agreement with a State pharmaceutical as-
 21 sistance program described in paragraph (2) to co-
 22 ordinate the coverage provided under the plan with
 23 the assistance provided under the State pharma-
 24 ceutical assistance program.

1 “(2) STATE PHARMACEUTICAL ASSISTANCE
2 PROGRAM DESCRIBED.—For purposes of paragraph
3 (1), a State pharmaceutical assistance program de-
4 scribed in this paragraph is a program that has been
5 established pursuant to a waiver under section 1115
6 or otherwise.

7 “(c) REGULATIONS TO CARRY OUT THIS PART.—

8 “(1) AUTHORITY FOR INTERIM FINAL REGULA-
9 TIONS.—The Secretary may promulgate initial regu-
10 lations implementing this part in interim final form
11 without prior opportunity for public comment.

12 “(2) FINAL REGULATIONS.—A final regulation
13 reflecting public comments must be published within
14 1 year of the interim final regulation promulgated
15 under paragraph (1).”.

16 “(d) WAIVER AUTHORITY.—The Secretary shall have
17 authority similar to the waiver authority under section
18 1857(i) to facilitate the offering of Medicare Prescription
19 Drug plans by employer or other group health plans as
20 part of employment-based retiree health coverage (as de-
21 fined in section 1860D-20(d)(4)(B)), including the au-
22 thority to establish separate premium amounts for enroll-
23 ees in a Medicare Prescription Drug plan by reason of
24 such coverage.”.

1 (b) CONFORMING AMENDMENTS TO FEDERAL SUP-
 2 PLEMENTARY MEDICAL INSURANCE TRUST FUND.—Sec-
 3 tion 1841 (42 U.S.C. 1395t) is amended—

4 (1) in the last sentence of subsection (a)—

5 (A) by striking “and” before “such
 6 amounts”; and

7 (B) by inserting before the period the fol-
 8 lowing: “, and such amounts as may be depos-
 9 ited in, or appropriated to, the Prescription
 10 Drug Account established by section 1860D-
 11 25”;

12 (2) in subsection (g), by inserting after “by this
 13 part,” the following: “the payments provided for
 14 under part D (in which case the payments shall be
 15 made from the Prescription Drug Account in the
 16 Trust Fund),”;

17 (3) in subsection (h), by inserting after
 18 “1840(d)” the following: “and sections 1860D-18
 19 and 1858A(e) (in which case the payments shall be
 20 made from the Prescription Drug Account in the
 21 Trust Fund)”;

22 (4) in subsection (i), by inserting after “section
 23 1840(b)(1)” the following: “, sections 1860D-18
 24 and 1858A(e) (in which case the payments shall be

1 made from the Prescription Drug Account in the
2 Trust Fund),”.

3 (c) CONFORMING REFERENCES TO PREVIOUS PART

4 D.—Any reference in law (in effect before the date of en-
5 actment of this Act) to part D of title XVIII of the Social
6 Security Act is deemed a reference to part F of such title
7 (as in effect after such date).

8 (d) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not
9 later than 6 months after the date of the enactment of
10 this Act, the Secretary shall submit to the appropriate
11 committees of Congress a legislative proposal providing for
12 such technical and conforming amendments in the law as
13 are required by the provisions of this Act.

14 **SEC. 102. STUDY AND REPORT ON PERMITTING PART B**
15 **ONLY INDIVIDUALS TO ENROLL IN MEDICARE**
16 **VOLUNTARY PRESCRIPTION DRUG DELIVERY**
17 **PROGRAM.**

18 (a) STUDY.—The Administrator of the Center for
19 Medicare Choices (as established under section 1808 of
20 the Social Security Act, as added by section 301(a)) shall
21 conduct a study on the need for rules relating to permit-
22 ting individuals who are enrolled under part B of title
23 XVIII of the Social Security Act but are not entitled to
24 benefits under part A of such title to buy into the medicare

1 voluntary prescription drug delivery program under part
 2 D of such title (as so added).

3 (b) REPORT.—Not later than January 1, 2005, the
 4 Administrator of the Center for Medicare Choices shall
 5 submit a report to Congress on the study conducted under
 6 subsection (a), together with any recommendations for leg-
 7 islation that the Administrator determines to be appro-
 8 priate as a result of such study.

9 **SEC. 103. RULES RELATING TO MEDIGAP POLICIES THAT**
 10 **PROVIDE PRESCRIPTION DRUG COVERAGE.**

11 (a) RULES RELATING TO MEDIGAP POLICIES THAT
 12 PROVIDE PRESCRIPTION DRUG COVERAGE.—Section
 13 1882 (42 U.S.C. 1395ss) is amended by adding at the end
 14 the following new subsection:

15 “(v) RULES RELATING TO MEDIGAP POLICIES THAT
 16 PROVIDE PRESCRIPTION DRUG COVERAGE.—

17 “(1) PROHIBITION ON SALE, ISSUANCE, AND
 18 RENEWAL OF POLICIES THAT PROVIDE PRESCRIP-
 19 TION DRUG COVERAGE TO PART D ENROLLEES.—

20 “(A) IN GENERAL.—Notwithstanding any
 21 other provision of law, on or after January 1,
 22 2006, no medicare supplemental policy that
 23 provides coverage of expenses for prescription
 24 drugs may be sold, issued, or renewed under

1 this section to an individual who is enrolled
2 under part D.

3 “(B) PENALTIES.—The penalties described
4 in subsection (d)(3)(A)(ii) shall apply with re-
5 spect to a violation of subparagraph (A).

6 “(2) ISSUANCE OF SUBSTITUTE POLICIES IF
7 THE POLICYHOLDER OBTAINS PRESCRIPTION DRUG
8 COVERAGE UNDER PART D.—

9 “(A) IN GENERAL.—The issuer of a medi-
10 care supplemental policy—

11 “(i) may not deny or condition the
12 issuance or effectiveness of a medicare
13 supplemental policy that has a benefit
14 package classified as ‘A’, ‘B’, ‘C’, ‘D’, ‘E’,
15 ‘F’ (including the benefit package classi-
16 fied as ‘F’ with a high deductible feature,
17 as described in subsection (p)(11)), or ‘G’
18 (under the standards established under
19 subsection (p)(2)) and that is offered and
20 is available for issuance to new enrollees by
21 such issuer;

22 “(ii) may not discriminate in the pric-
23 ing of such policy, because of health sta-
24 tus, claims experience, receipt of health
25 care, or medical condition; and

“(iii) may not impose an exclusion of
 benefits based on a pre-existing condition
 under such policy,
 in the case of an individual described in sub-
 paragraph (B) who seeks to enroll under the
 policy during the open enrollment period estab-
 lished under section 1860D-2(b)(2) and who
 submits evidence that they meet the require-
 ments under subparagraph (B) along with the
 application for such medicare supplemental pol-
 icy.

“(B) INDIVIDUAL DESCRIBED.—An indi-
 vidual described in this subparagraph is an in-
 dividual who—

“(i) enrolls in the medicare prescrip-
 tion drug delivery program under part D;
 and

“(ii) at the time of such enrollment
 was enrolled and terminates enrollment in
 a medicare supplemental policy which has
 a benefit package classified as ‘H’, ‘I’, or
 ‘J’ (including the benefit package classified
 as ‘J’ with a high deductible feature, as
 described in section 1882(p)(11)) under
 the standards referred to in subparagraph

(A)(i) or terminates enrollment in a policy to which such standards do not apply but which provides benefits for prescription drugs.

“(C) ENFORCEMENT.—The provisions of subparagraph (A) shall be enforced as though they were included in subsection (s).

“(3) NOTICE REQUIRED TO BE PROVIDED TO CURRENT POLICYHOLDERS WITH PRESCRIPTION DRUG COVERAGE.—No medicare supplemental policy of an issuer shall be deemed to meet the standards in subsection (c) unless the issuer provides written notice during the 60-day period immediately preceding the period established for the open enrollment period established under section 1860D-2(b)(2), to each individual who is a policyholder or certificate holder of a medicare supplemental policy issued by that issuer that provides some coverage of expenses for prescription drugs (at the most recent available address of that individual) of—

“(A) the ability to enroll in a new medicare supplemental policy pursuant to paragraph (2); and

“(B) the fact that, so long as such individual retains coverage under such policy, the

individual shall be ineligible for coverage of prescription drugs under part D.”.

(b) RULE OF CONSTRUCTION (1) IN GENERAL.—

Nothing in this Act shall be construed to require an issuer of a medicare supplemental policy under section 1882 of the Social Security Act (42 U.S.C. 1395rr) to participate as an eligible entity under part D of such Act, as added by section 101, as a condition for issuing such policy.

(2) PROHIBITION ON STATE REQUIREMENT.—A

State may not require an issuer of a medicare supplemental policy under section 1882 of the Social Security Act (42 U.S.C. 1395rr) to participate as an eligible entity under part D of such Act, as added by section 101, as a condition for issuing such policy.

SEC. 104. MEDICAID AND OTHER AMENDMENTS RELATED TO LOW-INCOME BENEFICIARIES.

(a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME SUBSIDIES.—Section 1902(a) (42 U.S.C. 1396a(a)) is amended—

- (1) by striking “and” at the end of paragraph (64);
- (2) by striking the period at the end of paragraph (65) and inserting “; and”; and

1 (3) by inserting after paragraph (65) the fol-
 2 lowing new paragraph:

3 “(66) provide for making eligibility determina-
 4 tions under section 1935(a).”.

5 (b) NEW SECTION.—

6 (1) IN GENERAL.—Title XIX (42 U.S.C. 1396
 7 et seq.) is amended—

8 (A) by redesignating section 1935 as sec-
 9 tion 1936; and

10 (B) by inserting after section 1934 the fol-
 11 lowing new section:

12 “SPECIAL PROVISIONS RELATING TO MEDICARE
 13 PRESCRIPTION DRUG BENEFIT

14 “SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGI-
 15 BILITY DETERMINATIONS FOR LOW-INCOME SUB-
 16 SIDIES.—As a condition of its State plan under this title
 17 under section 1902(a)(66) and receipt of any Federal fi-
 18 nancial assistance under section 1903(a), a State shall
 19 satisfy the following:

20 “(1) DETERMINATION OF ELIGIBILITY FOR
 21 TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE
 22 CARD PROGRAM FOR ELIGIBLE LOW-INCOME BENE-
 23 FICIARIES.—For purposes of section 1807A, submit
 24 to the Secretary an eligibility plan under which the
 25 State—

“(A) establishes eligibility standards consistent with the provisions of that section;

“(B) establishes procedures for providing presumptive eligibility for eligible low-income beneficiaries (as defined in section 1807A(i)(2)) under that section;

“(C) makes determinations of eligibility and income for purposes of identifying eligible low-income beneficiaries (as so defined) under that section; and

“(D) communicates to the Secretary determinations of eligibility or discontinuation of eligibility under that section for purposes of notifying prescription drug card sponsors under that section of the identity of eligible medicare low-income beneficiaries.

“(2) DETERMINATION OF ELIGIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER PART D OF TITLE XVIII FOR LOW-INCOME INDIVIDUALS.—Beginning November 1, 2005, for purposes of section 1860D–19—

“(A) make determinations of eligibility for premium and cost-sharing subsidies under and in accordance with such section;

1 “(B) establish procedures for providing
2 presumptive eligibility for individuals eligible for
3 subsidies under that section;

4 “(C) inform the Administrator of the Cen-
5 ter for Medicare Choices of such determinations
6 in cases in which such eligibility is established;
7 and

8 “(D) otherwise provide such Administrator
9 with such information as may be required to
10 carry out part D of title XVIII (including sec-
11 tion 1860D-19).

12 “(3) AGREEMENT TO ESTABLISH INFORMATION
13 AND ENROLLMENT SITES AT SOCIAL SECURITY
14 FIELD OFFICES.—Enter into an agreement with the
15 Commissioner of Social Security to use all Social Se-
16 curity field offices located in the State as informa-
17 tion and enrollment sites for making the eligibility
18 determinations required under paragraphs (1) and
19 (2).

20 “(4) SCREEN AND ENROLL INDIVIDUALS ELIGI-
21 BLE FOR MEDICARE COST-SHARING.—As part of
22 making an eligibility determination required under
23 paragraph (1) or (2), screen an individual who ap-
24 plies for such a determination for eligibility for med-
25 ical assistance for any medicare cost-sharing de-

scribed in section 1905(p)(3) and, if the individual is eligible for any such medicare cost-sharing, enroll the individual under the State plan (or under a waiver of such plan).

“(b) FEDERAL SUBSIDY OF ADMINISTRATIVE COSTS.—

“(1) ENHANCED MATCH FOR ELIGIBILITY DETERMINATIONS.—Subject to paragraphs (2) and (4), with respect to calendar quarters beginning on or after January 1, 2004, the amounts expended by a State in carrying out subsection (a) are expenditures reimbursable under section 1903(a)(7) except that, in applying such section with respect to such expenditures incurred for—

“(A) such calendar quarters occurring in fiscal year 2004 or 2005, ‘75 percent’ shall be substituted for ‘50 per centum’;

“(B) calendar quarters occurring in fiscal year 2006, ‘70 percent’ shall be substituted for ‘50 per centum’;

“(C) calendar quarters occurring in fiscal year 2007, ‘65 percent’ shall be substituted for ‘50 per centum’; and

1 “(D) calendar quarters occurring in fiscal
2 year 2008 or any fiscal year thereafter, ‘60 per-
3 cent’ shall be substituted for ‘50 per centum’.

4 “(2) 100 PERCENT MATCH FOR ELIGIBILITY
5 DETERMINATIONS FOR SUBSIDY-ELIGIBLE INDIVID-
6 UALS.—In the case of amounts expended by a State
7 on or after November 1, 2005, to determine whether
8 an individual is a subsidy-eligible individual for pur-
9 poses of section 1860D–19, such expenditures shall
10 be reimbursed under section 1903(a)(7) by sub-
11 stituting ‘100 percent’ for ‘50 per centum’.

12 “(3) ENHANCED MATCH FOR UPDATES OR IM-
13 PROVEMENTS TO ELIGIBILITY DETERMINATION SYS-
14 TEMS.—With respect to calendar quarters occurring
15 in fiscal year 2004, 2005, or 2006, the Secretary, in
16 addition to amounts otherwise paid under section
17 1903(a), shall pay to each State which has a plan
18 approved under this title, for each such quarter an
19 amount equal to 90 percent of so much of the sums
20 expended during such quarter as are attributable to
21 the design, development, acquisition, or installation
22 of improved eligibility determination systems (includ-
23 ing hardware and software for such systems) in
24 order to carry out the requirements of subsection (a)
25 and section 1807A(h)(1). No payment shall be made

1 to a State under the preceding sentence unless the
2 State's improved eligibility determination system—

3 “(A) satisfies such standards for improve-
4 ment as the Secretary may establish; and

5 “(B) complies, and is compatible, with the
6 standards established under part C of title XI
7 and any regulations promulgated under section
8 264(c) of the Health Insurance Portability and
9 Accountability Act of 1996 (42 U.S.C. 1320d-
10 2 note).

11 “(4) COORDINATION.—The State shall provide
12 the Secretary with such information as may be nec-
13 essary to properly allocate expenditures described in
14 paragraph (1), (2), or (3) that may otherwise be
15 made for similar eligibility determinations or expend-
16 itures.

17 “(c) FEDERAL PAYMENT OF MEDICARE PART B
18 PREMIUM FOR STATES PROVIDING PRESCRIPTION DRUG
19 COVERAGE FOR DUAL ELIGIBLE INDIVIDUALS.—

20 “(1) IN GENERAL.—Subject to paragraph (4)
21 and notwithstanding section 1905(b), in the case of
22 a State that provides medical assistance for covered
23 drugs (as such term is defined in section
24 1860D(a)(2)) to dual eligible individuals under this
25 title that satisfies the minimum standards described

1 in paragraph (2), the Federal medical assistance
 2 percentage shall be 100 percent for medicare cost-
 3 sharing described in section 1905(p)(3)(A)(ii) (relat-
 4 ing to premiums under section 1839) for individ-
 5 uals—

6 “(A) who are dual eligible individuals or
 7 qualified medicare beneficiaries; and

8 “(B) whose income is at least the income
 9 required for an individual to be an eligible indi-
 10 vidual under section 1611 for purposes of the
 11 supplemental security income program (as de-
 12 termined under section 1612), but does not ex-
 13 ceed 100 percent of the poverty line (as defined
 14 in section 2110(c)(5)) applicable to a family of
 15 the size involved.

16 “(2) MINIMUM STANDARDS DESCRIBED.—For
 17 purposes of paragraph (1), the minimum standards
 18 described in this paragraph are the following:

19 “(A) In providing medical assistance for
 20 dual eligible individuals for such covered drugs,
 21 the State satisfies the requirements of this title
 22 (including limitations on cost-sharing imposed
 23 under section 1916) applicable to the provision
 24 of medical assistance for prescribed drugs to
 25 dual eligible individuals.

“(B) In providing medical assistance for dual eligible individuals for such covered drugs, the State provides such individuals with beneficiary protections that the Secretary determines are equivalent to the beneficiary protections applicable under section 1860D–5 to eligible entities offering a Medicare Prescription Drug plan under part D of title XVIII.

“(C) In providing medical assistance for dual eligible individuals for such covered drugs, the State does not impose a limitation on the number of prescriptions an individual may have filled.

“(3) NONAPPLICATION.—Section 1927(d)(2)(E) shall not apply to a State for purposes of providing medical assistance for covered drugs (as such term is defined in section 1860D(a)(2)) to dual eligible individuals that satisfies the minimum standards described in paragraph (2).

“(4) LIMITATION.—Paragraph (1) shall not apply to any State before January 1, 2006.

“(d) FEDERAL PAYMENT OF MEDICARE PART A COST-SHARING FOR CERTAIN STATES.—

“(1) IN GENERAL.—Subject to paragraph (2) and notwithstanding section 1905(b), in the case of

1 a State that, as of the date of enactment of the Pre-
 2 scription Drug and Medicare Improvement Act of
 3 2003, provides medical assistance for individuals de-
 4 scribed in section 1902(a)(10)(A)(ii)(X), the Fed-
 5 eral medical assistance percentage shall be 100 per-
 6 cent for medicare cost-sharing described in subpara-
 7 graphs (B) and (C) of section 1905(p)(3) (relating
 8 to coinsurance and deductibles established under
 9 title XVIII) for the individuals provided medical as-
 10 sistance under section 1902(a)(10)(A)(ii)(X), but
 11 only—

12 “(A) with respect to such medicare cost-
 13 sharing that is incurred under part A of title
 14 XVIII; and

15 “(B) for so long as the State elects to pro-
 16 vide medical assistance under section
 17 1902(a)(10)(A)(ii)(X).

18 “(2) LIMITATION.—Paragraph (1) shall not
 19 apply to any State before January 1, 2006.

20 “(e) TREATMENT OF TERRITORIES.—

21 “(1) IN GENERAL.—In the case of a State,
 22 other than the 50 States and the District of Colum-
 23 bia—

24 “(A) the previous provisions of this section
 25 shall not apply to residents of such State; and

“(B) if the State establishes a plan described in paragraph (2), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be further increased by the amount specified in paragraph (3).

“(2) PLAN.—The plan described in this paragraph is a plan that—

“(A) provides medical assistance with respect to the provision of covered drugs (as defined in section 1860D(a)(2)) to individuals described in subparagraph (A), (B), (C), or (D) of section 1860D–19(a)(3); and

“(B) ensures that additional amounts received by the State that are attributable to the operation of this subsection are used only for such assistance.

“(3) INCREASED AMOUNT.—

“(A) IN GENERAL.—The amount specified in this paragraph for a State for a fiscal year is equal to the product of—

“(i) the aggregate amount specified in subparagraph (B); and

“(ii) the amount specified in section 1108(g)(1) for that State, divided by the

1 sum of the amounts specified in such sec-
2 tion for all such States.

3 “(B) AGGREGATE AMOUNT.—The aggre-
4 gate amount specified in this subparagraph
5 for—

6 “(i) the last 3 quarters of fiscal year
7 2006, is equal to \$37,500,000;

8 “(ii) fiscal year 2007, is equal to
9 \$50,000,000; and

10 “(iii) any subsequent fiscal year, is
11 equal to the aggregate amount specified in
12 this subparagraph for the previous fiscal
13 year increased by the annual percentage
14 increase specified in section 1860D–6(c)(5)
15 for the calendar year beginning in such fis-
16 cal year.

17 “(4) NONAPPLICATION.—Section 1927(d)(2)(E)
18 shall not apply to a State described in paragraph (1)
19 for purposes of providing medical assistance de-
20 scribed in paragraph (2)(A).

21 “(5) REPORT.—The Secretary shall submit to
22 Congress a report on the application of this sub-
23 section and may include in the report such rec-
24 ommendations as the Secretary deems appropriate.

1 “(f) DEFINITIONS.—For purposes of this section, the
 2 terms ‘qualified medicare beneficiary’, ‘subsidy-eligible in-
 3 dividual’, and ‘dual eligible individual’ have the meanings
 4 given such terms in subparagraphs (A), (D), and (E), re-
 5 spectively, of section 1860D–19(a)(4).”.

6 (2) CONFORMING AMENDMENTS.—

7 (A) Section 1905(b) (42 U.S.C. 1396d(b))
 8 is amended by inserting “and subsections (c)(1)
 9 and (d)(1) of section 1935” after “1933(d)”.

10 (B) Section 1108(f) (42 U.S.C. 1308(f)) is
 11 amended by inserting “and section
 12 1935(e)(1)(B)” after “Subject to subsection
 13 (g)”.

14 (3) TRANSFER OF FEDERALLY ASSUMED POR-
 15 TIONS OF MEDICARE COST-SHARING.—

16 (A) TRANSFER OF ASSUMPTION OF PART B
 17 PREMIUM FOR STATES PROVIDING PRESCRIP-
 18 TION DRUG COVERAGE FOR DUAL ELIGIBLE IN-
 19 DIVIDUALS TO THE FEDERAL SUPPLEMENTARY
 20 MEDICAL INSURANCE TRUST FUND.—Section
 21 1841(f) (42 U.S.C. 1395t(f)) is amended—

22 (i) by inserting “(1)” after “(f)”; and

23 (ii) by adding at the end the following

24 new paragraph:

1 “(2) There shall be transferred periodically (but not
 2 less often than once each fiscal year) to the Trust Fund
 3 from the Treasury amounts which the Secretary of Health
 4 and Human Services shall have certified are equivalent to
 5 the amounts determined under section 1935(c)(1) with re-
 6 spect to all States for a fiscal year.”.

7 (B) TRANSFER OF ASSUMPTION OF PART A
 8 COST-SHARING FOR CERTAIN STATES.—Section
 9 1817(g) (42 U.S.C. 1395i(g)) is amended—

10 (i) by inserting “(1)” after “(g)”; and

11 (ii) by adding at the end the following

12 new paragraph:

13 “(2) There shall be transferred periodically (but not
 14 less often than once each fiscal year) to the Trust Fund
 15 from the Treasury amounts which the Secretary of Health
 16 and Human Services shall have certified are equivalent to
 17 the amounts determined under section 1935(d)(1) with re-
 18 spect to certain States for a fiscal year.”.

19 (4) AMENDMENT TO BEST PRICE.—Section
 20 1927(c)(1)(C)(i) (42 U.S.C. 1396r-8(e)(1)(C)(i)), as
 21 amended by section 111(b), is amended—

22 (A) by striking “and” at the end of sub-
 23 clause (IV);

24 (B) by striking the period at the end of
 25 subclause (V) and inserting “; and”; and

1 (C) by adding at the end the following new
 2 subclause:

3 “(VI) any prices charged which
 4 are negotiated under a Medicare Pre-
 5 scription Drug plan under part D of
 6 title XVIII with respect to covered
 7 drugs, under a Medicare Advantage
 8 plan under part C of such title with
 9 respect to such drugs, or under a
 10 qualified retiree prescription drug
 11 plan (as defined in section 1860D-
 12 20(f)(1)) with respect to such drugs,
 13 on behalf of eligible beneficiaries (as
 14 defined in section 1860D(a)(3)).”.

15 (c) EXTENSION OF MEDICARE COST-SHARING FOR
 16 PART B PREMIUM FOR QUALIFYING INDIVIDUALS
 17 THROUGH 2008.—

18 (1) IN GENERAL.—Section 1902(a)(10)(E)(iv)
 19 (42 U.S.C. 1396a(a)(10)(E)(iv)) is amended to read
 20 as follows:

21 “(iv) subject to sections 1933 and
 22 1905(p)(4), for making medical assistance
 23 available (but only for premiums payable with
 24 respect to months during the period beginning
 25 with January 1998, and ending with December

2008) for medicare cost-sharing described in section 1905(p)(3)(A)(ii) for individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds the income level established by the State under section 1905(p)(2) and is at least 120 percent, but less than 135 percent, of the official poverty line (referred to in such section) for a family of the size involved and who are not otherwise eligible for medical assistance under the State plan;”.

(2) TOTAL AMOUNT AVAILABLE FOR ALLOCATION.—Section 1933(c) (42 U.S.C. 1396u-3(c)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (D), by striking “and” at the end;

(ii) in subparagraph (E)—

(I) by striking “fiscal year 2002” and inserting “each of fiscal years 2002 through 2008”; and

(II) by striking the period and inserting “; and”; and

(iii) by adding at the end the following new subparagraph:

“(F) the first quarter of fiscal year 2009,
\$100,000,000.”; and

(B) in paragraph (2)(A), by striking “the
sum of” and all that follows through
“1902(a)(10)(E)(iv)(II) in the State; to” and
inserting “twice the total number of individuals
described in section 1902(a)(10)(E)(iv) in the
State; to”.

(d) OUTREACH BY THE COMMISSIONER OF SOCIAL
SECURITY.—Section 1144 (42 U.S.C. 1320b-14) is
amended—

(1) in the section heading, by inserting “AND
SUBSIDIES FOR LOW-INCOME INDIVIDUALS UNDER
TITLE XVIII” after “COST-SHARING”;

(2) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by inserting
“for the transitional prescription drug as-
sistance card program under section
1807A, or for premium and cost-sharing
subsidies under section 1860D-19” before
the semicolon; and

(ii) in subparagraph (B), by inserting
“, program, and subsidies” after “medical
assistance”; and

1 (B) in paragraph (2)—

2 (i) in the matter preceding subpara-
3 graph (A), by inserting “, the transitional
4 prescription drug assistance card program
5 under section 1807A, or premium and
6 cost-sharing subsidies under section
7 1860D–19” after “assistance”; and

8 (ii) in subparagraph (A), by striking
9 “such eligibility” and inserting “eligibility
10 for medicare cost-sharing under the med-
11 icaid program”; and

12 (3) in subsection (b)—

13 (A) in paragraph (1)(A), by inserting “,
14 for the transitional prescription drug assistance
15 card program under section 1807A, or for pre-
16 mium and cost-sharing subsidies for low-income
17 individuals under section 1860D–19” after
18 “1933”;

19 (B) in paragraph (2), by inserting “, pro-
20 gram, and subsidies” after “medical assist-
21 ance”; and

22 (C) by adding at the end the following:

23 “(3) AGREEMENTS TO ESTABLISH INFORMA-
24 TION AND ENROLLMENT SITES AT SOCIAL SECURITY
25 FIELD OFFICES.—

1 “(A) IN GENERAL.—The Commissioner
2 shall enter into an agreement with each State
3 operating a State plan under title XIX (includ-
4 ing under a waiver of such plan) to establish in-
5 formation and enrollment sites within all the
6 Social Security field offices located in the State
7 for purposes of—

8 ~~section~~“(i) the State determining the eligi-
9 bility of individuals residing in the State
10 for medical assistance for payment of the
11 cost of medicare cost-sharing under the
12 medicaid program pursuant to sections
13 1902(a)(10)(E) and 1933, the transitional
14 prescription drug assistance card program
15 under section 1807A, or premium and
16 cost-sharing subsidies under section
17 1860D–19; and

18 “(ii) enrolling individuals who are de-
19 termined eligible for such medical assist-
20 ance, program, or subsidies in the State
21 plan (or waiver), the transitional prescrip-
22 tion drug assistance card program under
23 section 1807A, or the appropriate category
24 for premium and cost-sharing subsidies
25 under section 1860D–19.

“(B) AGREEMENT TERMS.—The Secretary and the Commissioner jointly shall develop terms for the State agreements required under subparagraph (A) that shall specify the responsibilities of the State and the Commissioner in the establishment and operation of such sites.

7 “(C) AUTHORIZATION OF APPROPRIA-
8 TIONS.—There are authorized to be appro-
9 priated to the Commissioner, such sums as may
10 be necessary to carry out this paragraph.”.

(e) REPORT REGARDING VOLUNTARY ENROLLMENT OF DUAL ELIGIBLE INDIVIDUALS IN PART D.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains such recommendations for legislation as the Secretary determines are necessary in order to establish a voluntary option for dual eligible individuals (as defined in 1860D–19(a)(4)(E) of the Social Security Act (as added by section 101)) to enroll under part D of title XVIII of such Act for prescription drug coverage.

20 SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF
21 MEDICARE PAYMENT ADVISORY COMMISSION
22 (MEDPAC).

23 (a) EXPANSION OF MEMBERSHIP.—

24 (1) IN GENERAL.—Section 1805(c) (42 U.S.C.
25 1395b-6(c)) is amended—

(A) in paragraph (1), by striking “17” and inserting “19”; and

(B) in paragraph (2)(B), by inserting “experts in the area of pharmacology and prescription drug benefit programs,” after “other health professionals,”.

(2) INITIAL TERMS OF ADDITIONAL MEMBERS.—

(A) IN GENERAL.—For purposes of staggering the initial terms of members of the Medicare Payment Advisory Commission under section 1805(c)(3) of the Social Security Act (42 U.S.C. 1395b–6(c)(3)), the initial terms of the 2 additional members of the Commission provided for by the amendment under paragraph (1)(A) are as follows:

(i) One member shall be appointed for 1 year.

(ii) One member shall be appointed for 2 years.

(B) COMMENCEMENT OF TERMS.—Such terms shall begin on January 1, 2005.

(b) EXPANSION OF DUTIES.—Section 1805(b)(2) (42 U.S.C. 1395b–6(b)(2)) is amended by adding at the end the following new subparagraph:

1 “(D) VOLUNTARY PRESCRIPTION DRUG
 2 DELIVERY PROGRAM.—Specifically, the Com-
 3 mission shall review, with respect to the vol-
 4 untary prescription drug delivery program
 5 under part D, competition among eligible enti-
 6 ties offering Medicare Prescription Drug plans
 7 and beneficiary access to such plans and cov-
 8 ered drugs, particularly in rural areas. As part
 9 of such review, the Commission shall hold 3
 10 field hearings in 2007.”.

11 **SEC. 106. STUDY REGARDING VARIATIONS IN SPENDING**
 12 **AND DRUG UTILIZATION.**

13 (a) STUDY.—The Secretary shall study on an ongo-
 14 ing basis variations in spending and drug utilization under
 15 part D of title XVIII of the Social Security Act for covered
 16 drugs to determine the impact of such variations on pre-
 17 miums imposed by eligible entities offering Medicare Pre-
 18 scription Drug plans under that part. In conducting such
 19 study, the Secretary shall examine the impact of geo-
 20 graphic adjustments of the monthly national average pre-
 21 mium under section 1860D–15 of such Act on—

22 (1) maximization of competition under part D
 23 of title XVIII of such Act; and

(2) the ability of eligible entities offering Medicare Prescription Drug plans to contain costs for covered drugs.

(b) REPORT.—Beginning with 2007, the Secretary shall submit annual reports to Congress on the study required under subsection (a).

**SEC. 107. LIMITATION ON PRESCRIPTION DRUG BENEFITS
OF MEMBERS OF CONGRESS.**

(a) LIMITATION ON BENEFITS.—Notwithstanding any other provision of law, during calendar year 2004, the actuarial value of the prescription drug benefit of any Member of Congress enrolled in a health benefits plan under chapter 89 of title 5, United States Code, may not exceed the actuarial value of any prescription drug benefit under title XVIII of the Social Security Act passed by the 1st session of the 108th Congress and enacted in law.

(b) REGULATIONS.—The Office of Personnel Management shall promulgate regulations to carry out this section.

SEC. 108. PROTECTING SENIORS WITH CANCER.

Any eligible beneficiary (as defined in section 1860D(3) of the Social Security Act) who is diagnosed with cancer shall be protected from high prescription drug costs in the following manner:

(1) SUBSIDY ELIGIBLE INDIVIDUALS WITH AN INCOME BELOW 100 PERCENT OF THE FEDERAL POVERTY LINE.—If the individual is a qualified medicare beneficiary (as defined in section 1860D–19(a)(4) of such Act), such individual shall receive the full premium subsidy and reduction of cost-sharing described in section 1860D–19(a)(1) of such Act, including the payment of—

(A) no deductible;

(B) no monthly beneficiary premium for at least one Medicare Prescription Drug plan available in the area in which the individual resides; and

(C) reduced cost-sharing described in subparagraphs (C), (D), and (E) of section 1860D–19(a)(1) of such Act.

(2) SUBSIDY ELIGIBLE INDIVIDUALS WITH AN INCOME BETWEEN 100 AND 135 PERCENT OF THE FEDERAL POVERTY LINE.—If the individual is a specified low income medicare beneficiary (as defined in paragraph 1860D–19(4)(B) of such Act) or a qualifying individual (as defined in paragraph 1860D–19(4)(C) of such Act) who is diagnosed with cancer, such individual shall receive the full premium subsidy and reduction of cost-sharing described in

1 section 1860D–19(a)(2) of such Act, including pay-
 2 ment of—

3 (A) no deductible;

4 (B) no monthly premium for any Medicare
 5 Prescription Drug plan described paragraph (1)
 6 or (2) of section 1860D–17(a) of such Act; and

7 (C) reduced cost-sharing described in sub-
 8 paragraphs (C), (D), and (E) of section
 9 1860D–19(a)(2) of such Act.

10 (3) SUBSIDY-ELIGIBLE INDIVIDUALS WITH IN-
 11 COME BETWEEN 135 PERCENT AND 160 PERCENT OF
 12 THE FEDERAL POVERTY LEVEL.—If the individual is
 13 a subsidy-eligible individual (as defined in section
 14 1860D–19(a)(4)(D) of such Act) who is diagnosed
 15 with cancer, such individual shall receive sliding
 16 scale premium subsidy and reduction of cost-sharing
 17 for subsidy-eligible individuals, including payment
 18 of—

19 (A) for 2006, a deductible of only \$50;

20 (B) only a percentage of the monthly pre-
 21 mium (as described in section 1860D–
 22 19(a)(3)(A)(i)); and

23 (C) reduced cost-sharing described in
 24 clauses (iii), (iv), and (v) of section 1860D–
 25 19(a)(3)(A).

(4) ELIGIBLE BENEFICIARIES WITH INCOME ABOVE 160 PERCENT OF THE FEDERAL POVERTY LEVEL.—If an individual is an eligible beneficiary (as defined in section 1860D(3) of such Act), is not described in paragraphs (1) through (3), and is diagnosed with cancer, such individual shall have access to qualified prescription drug coverage (as described in section 1860D–6(a)(1) of such Act), including payment of—

(A) for 2006, a deductible of \$275;

(B) the limits on cost-sharing described section 1860D–6(c)(2) of such Act up to, for 2006, an initial coverage limit of \$4,500; and

(C) for 2006, an annual out-of-pocket limit of \$3,700 with 10 percent cost-sharing after that limit is reached.

SEC. 109. PROTECTING SENIORS WITH CARDIOVASCULAR DISEASE, CANCER, OR ALZHEIMER'S DISEASE.

Any eligible beneficiary (as defined in section 1860D(3) of the Social Security Act) who is diagnosed with cardiovascular disease, cancer, diabetes or Alzheimer's disease shall be protected from high prescription drug costs in the following manner:

(1) SUBSIDY ELIGIBLE INDIVIDUALS WITH AN INCOME BELOW 100 PERCENT OF THE FEDERAL

1 POVERTY LINE.—If the individual is a qualified
 2 medicare beneficiary (as defined in section 1860D–
 3 19(a)(4) of such Act), such individual shall receive
 4 the full premium subsidy and reduction of cost-shar-
 5 ing described in section 1860D–19(a)(1) of such
 6 Act, including the payment of—

7 (A) no deductible;

8 (B) no monthly beneficiary premium for at
 9 least one Medicare Prescription Drug plan
 10 available in the area in which the individual re-
 11 sides; and

12 (C) reduced cost-sharing described in sub-
 13 paragraphs (C), (D), and (E) of section
 14 1860D–19(a)(1) of such Act.

15 (2) SUBSIDY ELIGIBLE INDIVIDUALS WITH AN
 16 INCOME BETWEEN 100 AND 135 PERCENT OF THE
 17 FEDERAL POVERTY LINE.—If the individual is a
 18 specified low income medicare beneficiary (as defined
 19 in paragraph 1860D–19(4)(B) of such Act) or a
 20 qualifying individual (as defined in paragraph
 21 1860D–19(4)(C) of such Act) who is diagnosed with
 22 cardiovascular disease, cancer, or Alzheimer's dis-
 23 ease, such individual shall receive the full premium
 24 subsidy and reduction of cost-sharing described in

1 section 1860D-19(a)(2) of such Act, including pay-
2 ment of—

3 (A) no deductible;

4 (B) no monthly premium for any Medicare
5 Prescription Drug plan described paragraph (1)
6 or (2) of section 1860D-17(a) of such Act; and

7 (C) reduced cost-sharing described in sub-
8 paragraphs (C), (D), and (E) of section
9 1860D-19(a)(2) of such Act.

10 (3) SUBSIDY-ELIGIBLE INDIVIDUALS WITH IN-
11 COME BETWEEN 135 PERCENT AND 160 PERCENT OF
12 THE FEDERAL POVERTY LEVEL.—If the individual is
13 a subsidy-eligible individual (as defined in section
14 1860D-19(a)(4)(D) of such Act) who is diagnosed
15 with cardiovascular disease, cancer, or Alzheimer's
16 disease, such individual shall receive sliding scale
17 premium subsidy and reduction of cost-sharing for
18 subsidy-eligible individuals, including payment of—

19 (A) for 2006, a deductible of only \$50;

20 (B) only a percentage of the monthly pre-
21 mium (as described in section 1860D-
22 19(a)(3)(A)(i)); and

23 (C) reduced cost-sharing described in
24 clauses (iii), (iv), and (v) of section 1860D-
25 19(a)(3)(A).

(4) ELIGIBLE BENEFICIARIES WITH INCOME ABOVE 160 PERCENT OF THE FEDERAL POVERTY LEVEL.—If an individual is an eligible beneficiary (as defined in section 1860D(3) of such Act), is not described in paragraphs (1) through (3), and is diagnosed with cardiovascular disease, cancer, or Alzheimer's disease, such individual shall have access to qualified prescription drug coverage (as described in section 1860D–6(a)(1) of such Act), including payment of—

(A) for 2006, a deductible of \$275;

(B) the limits on cost-sharing described section 1860D–6(c)(2) of such Act up to, for 2006, an initial coverage limit of \$4,500; and

(C) for 2006, an annual out-of-pocket limit of \$3,700 with 10 percent cost-sharing after that limit is reached.

SEC. 110. REVIEW AND REPORT ON CURRENT STANDARDS OF PRACTICE FOR PHARMACY SERVICES PROVIDED TO PATIENTS IN NURSING FACILITIES.

(a) REVIEW.—

(1) IN GENERAL.—The Secretary shall conduct a thorough review of the current standards of prac-

1 tice for pharmacy services provided to patients in
2 nursing facilities.

3 (2) SPECIFIC MATTERS REVIEWED.—In con-
4 ducting the review under paragraph (1), the Sec-
5 retary shall—

6 (A) assess the current standards of prac-
7 tice, clinical services, and other service require-
8 ments generally used for pharmacy services in
9 long-term care settings; and

10 (B) evaluate the impact of those standards
11 with respect to patient safety, reduction of
12 medication errors and quality of care.

13 (b) REPORT.—

14 (1) IN GENERAL.—Not later than the date that
15 is 18 months after the date of enactment of this Act,
16 the Secretary shall submit a report to Congress on
17 the study conducted under subsection (a)(1), to-
18 gether with any recommendations for legislation that
19 the Administrator determines to be appropriate as a
20 result of such study.

21 (2) CONTENTS.—The report submitted under
22 paragraph (1) shall contain—

23 (A) a detailed description of the plans of
24 the Secretary to implement the provisions of
25 this Act in a manner consistent with applicable

1 State and Federal laws designed to protect the
2 safety and quality of care of nursing facility pa-
3 tients; and

4 (B) recommendations regarding necessary
5 actions and appropriate reimbursement to en-
6 sure the provision of prescription drugs to
7 medicare beneficiaries residing in nursing facili-
8 ties in a manner consistent with existing patient
9 safety and quality of care standards under ap-
10 plicable State and Federal laws.

11 **SEC. 110A. MEDICATION THERAPY MANAGEMENT ASSESS-**
12 **MENT PROGRAM.**

13 (a) ESTABLISHMENT.—

14 (1) IN GENERAL.—The Secretary shall establish
15 an assessment program to contract with qualified
16 pharmacists to provide medication therapy manage-
17 ment services to eligible beneficiaries who receive
18 care under the original medicare fee-for-service pro-
19 gram under parts A and B of title XVIII of the So-
20 cial Security Act to eligible beneficiaries.

21 (2) SITES.—The Secretary shall designate 6 ge-
22 ographic areas, each containing not less than 3 sites,
23 at which to conduct the assessment program under
24 this section. At least 2 geographic areas designated
25 under this paragraph shall be located in rural areas.

1 (3) DURATION.—The Secretary shall conduct
2 the assessment program under this section for a 1-
3 year period.

4 (4) IMPLEMENTATION.—The Secretary shall
5 implement the program not later than January 1,
6 2005, but may not implement the assessment pro-
7 gram before October 1, 2004.

8 (b) PARTICIPANTS.—Any eligible beneficiary who re-
9 sides in an area designated by the Secretary as an assess-
10 ment site under subsection (a)(2) may participate in the
11 assessment program under this section if such beneficiary
12 identifies a qualified pharmacist who agrees to furnish
13 medication therapy management services to the eligible
14 beneficiary under the assessment program.

15 (c) CONTRACTS WITH QUALIFIED PHARMACISTS.—

16 (1) IN GENERAL.—The Secretary shall enter
17 into a contract with qualified pharmacists to provide
18 medication therapy management services to eligible
19 beneficiaries residing in the area served by the quali-
20 fied pharmacist.

21 (2) NUMBER OF QUALIFIED PHARMACISTS.—
22 The Secretary may contract with more than 1 quali-
23 fied pharmacist at each site.

24 (d) PAYMENT TO QUALIFIED PHARMACISTS.—

(1) IN GENERAL.—Under an contract entered into under subsection (c), the Secretary shall pay qualified pharmacists a fee for providing medication therapy management services.

(2) ASSESSMENT OF PAYMENT METHODOLOGIES.—The Secretary shall, in consultation with national pharmacist and pharmacy associations, design the fee paid under paragraph (1) to test various payment methodologies applicable with respect to medication therapy management services, including a payment methodology that applies a relative value scale and fee-schedule with respect to such services that take into account the differences in—

(A) the time required to perform the different types of medication therapy management services;

(B) the level of risk associated with the use of particular outpatient prescription drugs or groups of drugs; and

(C) the health status of individuals to whom such services are provided.

(e) FUNDING.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall provide for the transfer from the Federal Supplementary Insurance Trust Fund es-

1 tablished under section 1841 of the Social Security
 2 Act (42 U.S.C. 1395t) of such funds as are nec-
 3 essary for the costs of carrying out the assessment
 4 program under this section. *et seq.*

5 (2) BUDGET NEUTRALITY.—In conducting the
 6 assessment program under this section, the Sec-
 7 retary shall ensure that the aggregate payments
 8 made by the Secretary do not exceed the amount
 9 which the Secretary would have paid if the assess-
 10 ment program under this section was not imple-
 11 mented.

12 (f) WAIVER AUTHORITY.—The Secretary may waive
 13 such requirements of titles XI and XVIII of the Social
 14 Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as
 15 may be necessary for the purpose of carrying out the as-
 16 sessment program under this section. *et seq.*

17 (g) AVAILABILITY OF DATA.—During the period in
 18 which the assessment program is conducted, the Secretary
 19 annually shall make available data regarding—

20 (1) the geographic areas and sites designated
 21 under subsection (a)(2);

22 (2) the number of eligible beneficiaries partici-
 23 pating in the program under subsection (b) and the
 24 level and types medication therapy management
 25 services used by such beneficiaries;

(3) the number of qualified pharmacists with contracts under subsection (c), the location of such pharmacists, and the number of eligible beneficiaries served by such pharmacists; and

(4) the types of payment methodologies being tested under subsection (d)(2).

(h) REPORT.—

(1) IN GENERAL.—Not later than 6 months after the completion of the assessment program under this section, the Secretary shall submit to Congress a final report summarizing the final outcome of the program and evaluating the results of the program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

(2) ASSESSMENT OF PAYMENT METHODOLOGIES.—The final report submitted under paragraph (1) shall include an assessment of the feasibility and appropriateness of the various payment methodologies tested under subsection (d)(2).

(i) DEFINITIONS.—In this section:

(1) MEDICATION THERAPY MANAGEMENT SERVICES.—The term “medication therapy management services” means services or programs furnished by a qualified pharmacist to an eligible beneficiary, indi-

1 vidually or on behalf of a pharmacy provider, which
 2 are designed—

3 (A) to ensure that medications are used
 4 appropriately by such individual;

5 (B) to enhance the individual's under-
 6 standing of the appropriate use of medications;

7 (C) to increase the individual's compliance
 8 with prescription medication regimens;

9 (D) to reduce the risk of potential adverse
 10 events associated with medications; and

11 (E) to reduce the need for other costly
 12 medical services through better management of
 13 medication therapy.

14 (2) ELIGIBLE BENEFICIARY.—The term “eligi-
 15 ble beneficiary” means an individual who is—

16 (A) entitled to (or enrolled for) benefits
 17 under part A and enrolled for benefits under
 18 part B of the Social Security Act (42 U.S.C.
 19 1395c et seq.; 1395j et seq.);

20 (B) not enrolled with a Medicare+Choice
 21 plan or a MedicareAdvantage plan under part
 22 C; and

23 (C) receiving, in accordance with State law
 24 or regulation, medication for—

(i) the treatment of asthma, diabetes,
 or chronic cardiovascular disease, including
 an individual on anticoagulation or lipid
 reducing medications; or
 (ii) such other chronic diseases as the
 Secretary may specify.

(3) QUALIFIED PHARMACIST.—The term
 “qualified pharmacist” means an individual who is a
 licensed pharmacist in good standing with the State
 Board of Pharmacy.

Subtitle B—Medicare Prescription Drug Discount Card and Transi- tional Assistance for Low-In- come Beneficiaries

SEC. 111. MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE FOR LOW-INCOME BENEFICIARIES.

(a) IN GENERAL.—Title XVIII is amended by insert-
 ing after section 1806 the following new sections:

“MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT PROGRAM

“SEC. 1807. (a) ESTABLISHMENT.—There is estab-
 lished a medicare prescription drug discount card endorse-
 ment program under which the Secretary shall—

1 “(1) endorse prescription drug discount card
2 programs offered by prescription drug card sponsors
3 that meet the requirements of this section; and

4 “(2) make available to eligible beneficiaries in-
5 formation regarding such endorsed programs.

6 “(b) ELIGIBILITY, ELECTION OF PROGRAM, AND EN-
7 ROLLMENT FEES.—

8 “(1) ELIGIBILITY AND ELECTION OF PRO-
9 GRAM.—

10 “(A) IN GENERAL.—Subject to subpara-
11 graph (B), the Secretary shall establish proce-
12 dures—

13 “(i) for identifying eligible bene-
14 ficiaries; and

15 “(ii) under which such beneficiaries
16 may make an election to enroll in any pre-
17 scription drug discount card program en-
18 dorsed under this section and disenroll
19 from such a program.

20 “(B) LIMITATION.—An eligible beneficiary
21 may not be enrolled in more than 1 prescription
22 drug discount card program at any time.

23 “(2) ENROLLMENT FEES.—

24 “(A) IN GENERAL.—A prescription drug
25 card sponsor may charge an annual enrollment

fee to each eligible beneficiary enrolled in a prescription drug discount card program offered by such sponsor.

“(B) AMOUNT.—No enrollment fee charged under subparagraph (A) may exceed \$25.

“(C) UNIFORM ENROLLMENT FEE.—A prescription drug card sponsor shall ensure that the enrollment fee for a prescription drug discount card program endorsed under this section is the same for all eligible medicare beneficiaries enrolled in the program.

“(D) COLLECTION.—Any enrollment fee shall be collected by the prescription drug card sponsor.

“(c) PROVIDING INFORMATION TO ELIGIBLE BENEFICIARIES.—

“(1) PROMOTION OF INFORMED CHOICE.—

“(A) BY THE SECRETARY.—In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which compares the costs and benefits of such programs. Such dissemination shall

1 be coordinated with the dissemination of edu-
2 cational information on other medicare options.

3 “(B) BY PRESCRIPTION DRUG CARD SPON-
4 SORS.—Each prescription drug card sponsor
5 shall make available to each eligible beneficiary
6 (through the Internet and otherwise) informa-
7 tion—

8 “(i) that the Secretary identifies as
9 being necessary to promote informed
10 choice among endorsed prescription drug
11 discount card programs by eligible bene-
12 ficiaries, including information on enroll-
13 ment fees, negotiated prices for prescrip-
14 tion drugs charged to beneficiaries, and
15 services relating to prescription drugs of-
16 fered under the program;

17 “(ii) on how any formulary used by
18 such sponsor functions.

19 “(2) USE OF MEDICARE TOLL-FREE NUMBER.—
20 The Secretary shall provide through the 1-800-
21 MEDICARE toll free telephone number for the re-
22 ceipt and response to inquiries and complaints con-
23 cerning the medicare prescription drug discount card
24 endorsement program established under this section

1 and prescription drug discount card programs en-
2 dored under such program.

3 “(d) BENEFICIARY PROTECTIONS.—

4 “(1) IN GENERAL.—Each prescription drug dis-
5 count card program endorsed under this section
6 shall meet such requirements as the Secretary iden-
7 tifies to protect and promote the interest of eligible
8 beneficiaries, including requirements that—

9 “(A) relate to appeals by eligible bene-
10 ficiaries and marketing practices; and

11 “(B) ensure that beneficiaries are not
12 charged more than the lower of the negotiated
13 retail price or the usual and customary price.

14 “(2) ENSURING PHARMACY ACCESS.—Each pre-
15 scription drug card sponsor offering a prescription
16 drug discount card program endorsed under this sec-
17 tion shall secure the participation in its network of
18 a sufficient number of pharmacies that dispense
19 (other than by mail order) drugs directly to patients
20 to ensure convenient access (as determined by the
21 Secretary and including adequate emergency access)
22 for enrolled beneficiaries. Such standards shall take
23 into account reasonable distances to pharmacy serv-
24 ices in urban and rural areas and access to phar-

1 macy services of the Indian Health Service and In-
2 dian tribes and tribal organizations.

3 “(3) QUALITY ASSURANCE.—Each prescription
4 drug card sponsor offering a prescription drug dis-
5 count card program endorsed under this section
6 shall have in place adequate procedures for assuring
7 that quality service is provided to eligible bene-
8 ficiaries enrolled in a prescription drug discount
9 card program offered by such sponsor.

10 “(4) CONFIDENTIALITY OF ENROLLEE
11 RECORDS.—Insofar as a prescription drug card
12 sponsor maintains individually identifiable medical
13 records or other health information regarding eligi-
14 ble beneficiaries enrolled in a prescription drug dis-
15 count card program endorsed under this section, the
16 prescription drug card sponsor shall have in place
17 procedures to safeguard the privacy of any individ-
18 ually identifiable beneficiary information in a man-
19 ner that the Secretary determines is consistent with
20 the Federal regulations (concerning the privacy of
21 individually identifiable health information) promul-
22 gated under section 264(c) of the Health Insurance
23 Portability and Accountability Act of 1996.

24 “(5) NO OTHER FEES.—A prescription drug
25 card sponsor may not charge any fee to an eligible

beneficiary under a prescription drug discount card program endorsed under this section other than an enrollment fee charged under subsection (b)(2)(A).

“(6) PRICES.—

“(A) AVOIDANCE OF HIGH PRICED DRUGS.—A prescription drug card sponsor may not recommend switching an eligible beneficiary to a drug with a higher negotiated price absent a recommendation by a licensed health professional that there is a clinical indication with respect to the patient for such a switch.

“(B) PRICE STABILITY.—Negotiated prices charged for prescription drugs covered under a prescription drug discount card program endorsed under this section may not change more frequently than once every 60 days.

“(e) PRESCRIPTION DRUG BENEFITS.—

“(1) IN GENERAL.—Each prescription drug card sponsor may only provide benefits that relate to prescription drugs (as defined in subsection (i)(2)) under a prescription drug discount card program endorsed under this section.

“(2) SAVINGS TO ELIGIBLE BENEFICIARIES.—

“(A) IN GENERAL.—Subject to subparagraph (D), each prescription drug card sponsor

1 shall provide eligible beneficiaries who enroll in
2 a prescription drug discount card program of-
3 fered by such sponsor that is endorsed under
4 this section with access to negotiated prices
5 used by the sponsor with respect to prescription
6 drugs dispensed to eligible beneficiaries.

7 “(B) INAPPLICABILITY OF MEDICAID BEST
8 PRICE RULES.—The requirements of section
9 1927 relating to manufacturer best price shall
10 not apply to the negotiated prices for prescrip-
11 tion drugs made available under a prescription
12 drug discount card program endorsed under
13 this section.

14 “(C) GUARANTEED ACCESS TO NEGO-
15 TIATED PRICES.—The Secretary, in consulta-
16 tion with the Inspector General of the Depart-
17 ment of Health and Human Services, shall es-
18 tablish procedures to ensure that eligible bene-
19 ficiaries have access to the negotiated prices for
20 prescription drugs provided under subparagraph
21 (A).

22 “(D) APPLICATION OF FORMULARY RE-
23 STRICTIONS.—A drug prescribed for an eligible
24 beneficiary that would otherwise be a covered
25 drug under this section shall not be so consid-

ered under a prescription drug discount card program if the program excludes the drug under a formulary.

“(3) BENEFICIARY SERVICES.—Each prescription drug discount card program endorsed under this section shall provide pharmaceutical support services, such as education, counseling, and services to prevent adverse drug interactions.

“(4) DISCOUNT CARDS.—Each prescription drug card sponsor shall issue a card to eligible beneficiaries enrolled in a prescription drug discount card program offered by such sponsor that the beneficiary may use to obtain benefits under the program.

“(f) SUBMISSION OF APPLICATIONS FOR ENDORSEMENT AND APPROVAL.—

“(1) SUBMISSION OF APPLICATIONS FOR ENDORSEMENT.—Each prescription drug card sponsor that seeks endorsement of a prescription drug discount card program under this section shall submit to the Secretary, at such time and in such manner as the Secretary may specify, such information as the Secretary may require.

“(2) APPROVAL.—The Secretary shall review the information submitted under paragraph (1) and

1 shall determine whether to endorse the prescription
 2 drug discount card program to which such informa-
 3 tion relates. The Secretary may not approve a pro-
 4 gram unless the program and prescription drug card
 5 sponsor offering the program comply with the re-
 6 quirements under this section.

7 “(g) REQUIREMENTS ON DEVELOPMENT AND APPLI-
 8 CATION OF FORMULARIES.—If a prescription drug card
 9 sponsor offering a prescription drug discount card pro-
 10 gram uses a formulary, the following requirements must
 11 be met:

12 “(1) PHARMACY AND THERAPEUTIC (P&T) COM-
 13 MITTEE.—

14 “(A) IN GENERAL.—The eligible entity
 15 must establish a pharmacy and therapeutic
 16 committee that develops and reviews the for-
 17 mulary.

18 “(B) COMPOSITION.—A pharmacy and
 19 therapeutic committee shall include at least 1
 20 academic expert, at least 1 practicing physician,
 21 and at least 1 practicing pharmacist, all of
 22 whom have expertise in the care of elderly or
 23 disabled persons, and a majority of the mem-
 24 bers of such committee shall consist of individ-

uals who are a practicing physician or a practicing pharmacist (or both).

“(2) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information as the committee determines to be appropriate.

“(3) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES AND CLASSES.—

“(A) IN GENERAL.—The formulary must include drugs within each therapeutic category and class of covered outpatient drugs (as defined by the Secretary), although not necessarily for all drugs within such categories and classes.

“(B) REQUIREMENT.—In defining therapeutic categories and classes of covered outpatient drugs pursuant to subparagraph (A), the Secretary shall use the compendia referred to section 1927(g)(1)(B)(i) or other recognized sources for categorizing drug therapeutic categories and classes.

1 “(4) PROVIDER EDUCATION.—The committee
2 shall establish policies and procedures to educate
3 and inform health care providers concerning the for-
4 mulary.

5 “(5) NOTICE BEFORE REMOVING DRUGS FROM
6 FORMULARY.—Any removal of a drug from a for-
7 mulary shall take effect only after appropriate notice
8 is made available to beneficiaries and pharmacies.

9 “(h) FRAUD AND ABUSE PREVENTION.—

10 “(1) IN GENERAL.—The Secretary shall provide
11 appropriate oversight to ensure compliance of en-
12 dorsed programs with the requirements of this sec-
13 tion, including verification of the negotiated prices
14 and services provided.

15 “(2) DISQUALIFICATION FOR ABUSIVE PRAC-
16 TICES.—The Secretary may implement intermediate
17 sanctions and may revoke the endorsement of a pro-
18 gram that the Secretary determines no longer meets
19 the requirements of this section or that has engaged
20 in false or misleading marketing practices.

21 “(3) AUTHORITY WITH RESPECT TO CIVIL
22 MONEY PENALTIES.—The Secretary may impose a
23 civil money penalty in an amount not to exceed
24 \$10,000 for any violation of this section. The provi-
25 sions of section 1128A (other than subsections (a)

1 and (b)) shall apply to a civil money penalty under
 2 the previous sentence in the same manner as such
 3 provisions apply to a penalty or proceeding under
 4 section 1128A(a).

5 “(4) REPORTING TO SECRETARY.—Each pre-
 6 scription drug card sponsor offering a prescription
 7 drug discount card program endorsed under this sec-
 8 tion shall report information relating to program
 9 performance, use of prescription drugs by eligible
 10 beneficiaries enrolled in the program, financial infor-
 11 mation of the sponsor, and such other information
 12 as the Secretary may specify. The Secretary may not
 13 disclose any proprietary data reported under this
 14 paragraph.

15 “(5) DRUG UTILIZATION REVIEW.—The Sec-
 16 retary may use claims data from parts A and B for
 17 purposes of conducting a drug utilization review pro-
 18 gram.

19 “(i) DEFINITIONS.—In this section:

20 “(1) ELIGIBLE BENEFICIARY.—

21 “(A) IN GENERAL.—The term ‘eligible
 22 beneficiary’ means an individual who—

23 “(i) is entitled to, or enrolled for, ben-
 24 efits under part A and enrolled under part
 25 B; and

1 “(ii) is not a dual eligible individual
2 (as defined in subparagraph (B)).

3 “(B) DUAL ELIGIBLE INDIVIDUAL.—

4 “(i) IN GENERAL.—The term ‘dual el-
5 igible individual’ means an individual who
6 is—

7 “(I) enrolled under title XIX or
8 under a waiver under section 1115 of
9 the requirements of such title for
10 medical assistance that is not less
11 than the medical assistance provided
12 to an individual described in section
13 1902(a)(10)(A)(i) and includes cov-
14 ered outpatient drugs (as such term is
15 defined for purposes of section 1927);
16 and

17 “(II) entitled to benefits under
18 part A and enrolled under part B.

19 “(ii) INCLUSION OF MEDICALLY
20 NEEDY.—Such term includes an individual
21 described in section 1902(a)(10)(C).

22 “(2) PRESCRIPTION DRUG.—

23 “(A) IN GENERAL.—Except as provided in
24 subparagraph (B), the term ‘prescription drug’
25 means—

1 “(i) a drug that may be dispensed
2 only upon a prescription and that is de-
3 scribed in clause (i) or (ii) of subparagraph
4 (A) of section 1927(k)(2); or

5 “(ii) a biological product or insulin de-
6 scribed in subparagraph (B) or (C) of such
7 section (including syringes, and necessary
8 medical supplies associated with the ad-
9 ministration of insulin, as defined by the
10 Secretary), *inserted text*

11 and such term includes a vaccine licensed under
12 section 351 of the Public Health Service Act
13 and any use of a covered outpatient drug for a
14 medically accepted indication (as defined in sec-
15 tion 1927(k)(6)).

16 “(B) EXCLUSIONS.—The term ‘prescrip-
17 tion drug’ does not include drugs or classes of
18 drugs, or their medical uses, which may be ex-
19 cluded from coverage or otherwise restricted
20 under section 1927(d)(2), other than subpara-
21 graph (E) thereof (relating to smoking ces-
22 sation agents), or under section 1927(d)(3).

23 “(3) NEGOTIATED PRICE.—The term ‘nego-
24 tiated price’ includes all discounts, direct or indirect

1 subsidies, rebates, price concessions, and direct or
2 indirect remunerations.

3 “(4) PRESCRIPTION DRUG CARD SPONSOR.—

4 The term ‘prescription drug card sponsor’ means
5 any entity with demonstrated experience and exper-
6 tise in operating a prescription drug discount card
7 program, an insurance program that provides cov-
8 erage for prescription drugs, or a similar program
9 that the Secretary determines to be appropriate to
10 provide eligible beneficiaries with the benefits under
11 a prescription drug discount card program endorsed
12 by the Secretary under this section, including—

13 “(A) a pharmaceutical benefit management
14 company;

15 “(B) a wholesale or retail pharmacist deliv-
16 ery system;

17 “(C) an insurer (including an insurer that
18 offers medicare supplemental policies under sec-
19 tion 1882);

20 “(D) any other entity; or

21 “(E) any combination of the entities de-
22 scribed in subparagraphs (A) through (D).

23 “TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE CARD
24 PROGRAM FOR ELIGIBLE LOW-INCOME BENEFICIARIES

25 “SEC. 1807A. (a) ESTABLISHMENT.—

1 “(1) IN GENERAL.—There is established a pro-
 2 gram under which the Secretary shall award con-
 3 tracts to prescription drug card sponsors offering a
 4 prescription drug discount card that has been en-
 5 dorsed by the Secretary under section 1807 under
 6 which such sponsors shall offer a prescription drug
 7 assistance card program to eligible low-income bene-
 8 ficiaries in accordance with the requirements of this
 9 section. *modified 10/1/00*

10 “(2) APPLICATION OF DISCOUNT CARD PROVI-
 11 SIONS.—Except as otherwise provided in this sec-
 12 tion, the provisions of section 1807 shall apply to
 13 the program established under this section.

14 “(b) ELIGIBILITY, ELECTION OF PROGRAM, AND EN-
 15 ROLLMENT FEES.— *modified 10/1/00*

16 “(1) ELIGIBILITY AND ELECTION OF PRO-
 17 GRAM.— *modified 10/1/00*

18 “(A) IN GENERAL.—Subject to the suc-
 19 ceeding provisions of this paragraph, the enroll-
 20 ment procedures established under section
 21 1807(b)(1)(A)(ii) shall apply for purposes of
 22 this section. *modified 10/1/00*

23 “(B) ENROLLMENT OF ANY ELIGIBLE
 24 LOW-INCOME BENEFICIARY.—Each prescription
 25 drug card sponsor offering a prescription drug

1 assistance card program under this section shall
2 permit any eligible low-income beneficiary to en-
3 roll in such program if it serves the geographic
4 area in which the beneficiary resides.

5 “(C) SIMULTANEOUS ENROLLMENT IN
6 PRESCRIPTION DRUG DISCOUNT CARD PRO-
7 GRAM.—An eligible low-income beneficiary who
8 enrolls in a prescription drug assistance card
9 program offered by a prescription drug card
10 sponsor under this section shall be simulta-
11 neously enrolled in a prescription drug discount
12 card program offered by such sponsor. S1

13 “(2) WAIVER OF ENROLLMENT FEES.—

14 “(A) IN GENERAL.—A prescription drug
15 card sponsor may not charge an enrollment fee
16 to any eligible low-income beneficiary enrolled
17 in a prescription drug discount card program
18 offered by such sponsor.

19 “(B) PAYMENT BY SECRETARY.—Under a
20 contract awarded under subsection (f)(2), the
21 Secretary shall pay to each prescription drug
22 card sponsor an amount equal to any enroll-
23 ment fee charged under section 1807(b)(2)(A)
24 on behalf of each eligible low-income beneficiary
25 enrolled in a prescription drug discount card

1 program under paragraph (1)(C) offered by
2 such sponsor.

3 “(c) ADDITIONAL BENEFICIARY PROTECTIONS.—

4 “(1) PROVIDING INFORMATION TO ELIGIBLE
5 LOW-INCOME BENEFICIARIES.—In addition to the in-
6 formation provided to eligible beneficiaries under
7 section 1807(c), the prescription drug card sponsor
8 shall—

9 “(A) periodically notify each eligible low-in-
10 come beneficiary enrolled in a prescription drug
11 assistance card program offered by such spon-
12 sor of the amount of coverage for prescription
13 drugs remaining under subsection (d)(2)(A);
14 and

15 “(B) notify each eligible low-income bene-
16 ficiary enrolled in a prescription drug assistance
17 card program offered by such sponsor of the
18 grievance and appeals processes under the pro-
19 gram.

20 “(2) CONVENIENT ACCESS IN LONG-TERM CARE
21 FACILITIES.—For purposes of determining whether
22 convenient access has been provided under section
23 1807(d)(2) with respect to eligible low-income bene-
24 ficiaries enrolled in a prescription drug assistance
25 card program, the Secretary may only make a deter-

1 determination that such access has been provided if an
 2 appropriate arrangement is in place for eligible low-
 3 income beneficiaries who are in a long-term care fa-
 4 cility (as defined by the Secretary) to receive pre-
 5 scription drug benefits under the program.

6 “(3) COORDINATION OF BENEFITS.—

7 “(A) IN GENERAL.—The Secretary shall
 8 establish procedures under which eligible low-in-
 9 come beneficiaries who are enrolled for coverage
 10 described in subparagraph (B) and enrolled in
 11 a prescription drug assistance card program
 12 have access to the prescription drug benefits
 13 available under such program.

14 “(B) COVERAGE DESCRIBED.—Coverage
 15 described in this subparagraph is as follows:

16 “(i) Coverage of prescription drugs
 17 under a State pharmaceutical assistance
 18 program.

19 “(ii) Enrollment in a
 20 Medicare+Choice plan under part C.

21 “(4) GRIEVANCE MECHANISM.—Each prescrip-
 22 tion drug card sponsor with a contract under this
 23 section shall provide in accordance with section
 24 1852(f) meaningful procedures for hearing and re-
 25 solving grievances between the prescription drug

1 card sponsor (including any entity or individual
2 through which the prescription drug card sponsor
3 provides covered benefits) and enrollees in a pre-
4 scription drug assistance card program offered by
5 such sponsor. ~~edit not needed/german~~

6 “(5) APPLICATION OF COVERAGE DETERMINA-
7 TION AND RECONSIDERATION PROVISIONS.—

8 “(A) IN GENERAL.—The requirements of
9 paragraphs (1) through (3) of section 1852(g)
10 shall apply with respect to covered benefits
11 under a prescription drug assistance card pro-
12 gram under this section in the same manner as
13 such requirements apply to a Medicare+Choice
14 organization with respect to benefits it offers
15 under a Medicare+Choice plan under part C.

16 “(B) REQUEST FOR REVIEW OF TIERED
17 FORMULARY DETERMINATIONS.—In the case of
18 a prescription drug assistance card program of-
19 fered by a prescription drug card sponsor that
20 provides for tiered pricing for drugs included
21 within a formulary and provides lower prices for
22 preferred drugs included within the formulary,
23 an eligible low-income beneficiary who is en-
24 rolled in the program may request coverage of
25 a nonpreferred drug under the terms applicable

1 for preferred drugs if the prescribing physician
2 determines that the preferred drug for treat-
3 ment of the same condition is not as effective
4 for the eligible low-income beneficiary or has
5 adverse effects for the eligible low-income bene-
6 ficiary.

7 “(C) FORMULARY DETERMINATIONS.—An
8 eligible low-income beneficiary who is enrolled
9 in a prescription drug assistance card program
10 offered by a prescription drug card sponsor may
11 appeal to obtain coverage for a covered drug
12 that is not on a formulary of the entity if the
13 prescribing physician determines that the for-
14 mulary drug for treatment of the same condi-
15 tion is not as effective for the eligible low-in-
16 come beneficiary or has adverse effects for the
17 eligible low-income beneficiary.

18 “(6) APPEALS.—

19 “(A) IN GENERAL.—Subject to subpara-
20 graph (B), a prescription drug card sponsor
21 shall meet the requirements of paragraphs (4)
22 and (5) of section 1852(g) with respect to
23 drugs not included on any formulary in a simi-
24 lar manner (as determined by the Secretary) as
25 such requirements apply to a Medicare+Choice

organization with respect to benefits it offers under a Medicare+Choice plan under part C.

“(B) FORMULARY DETERMINATIONS.—An eligible low-income beneficiary who is enrolled in a prescription drug assistance card program offered by a prescription drug card sponsor may appeal to obtain coverage for a covered drug that is not on a formulary of the entity if the prescribing physician determines that the formulary drug for treatment of the same condition is not as effective for the eligible low-income beneficiary or has adverse effects for the eligible low-income beneficiary.

“(C) APPEALS AND EXCEPTIONS TO APPLICATION.—The prescription drug card sponsor must have, as part of the appeals process under this paragraph, a process for timely appeals for denials of coverage based on the application of the formulary.

“(d) PRESCRIPTION DRUG BENEFITS.—

“(1) IN GENERAL.—Subject to paragraph (5), all the benefits available under a prescription drug discount card program offered by a prescription drug card sponsor and endorsed under section 1807 shall be available to eligible low-income beneficiaries

1 enrolled in a prescription drug assistance card pro-
 2 gram offered by such sponsor.

3 “(2) ASSISTANCE FOR ELIGIBLE LOW-INCOME
 4 BENEFICIARIES.—

5 “(A) \$600 ANNUAL ASSISTANCE.—Subject
 6 to subparagraphs (B) and (C) and paragraph
 7 (5), each prescription drug card sponsor with a
 8 contract under this section shall provide cov-
 9 erage for the first \$600 of expenses for pre-
 10 scription drugs incurred during each calendar
 11 year by an eligible low-income beneficiary en-
 12 rolled in a prescription drug assistance card
 13 program offered by such sponsor.

14 “(B) COINSURANCE.—

15 “(i) IN GENERAL.—The prescription
 16 drug card sponsor shall determine an
 17 amount of coinsurance to collect from each
 18 eligible low-income beneficiary enrolled in a
 19 prescription drug assistance card program
 20 offered by such sponsor for which coverage
 21 is available under subparagraph (A).

22 “(ii) AMOUNT.—The amount of coin-
 23 surance collected under clause (i) shall be
 24 at least 10 percent of the negotiated price

1 of each prescription drug dispensed to an
2 eligible low-income beneficiary.

3 “(iii) CONSTRUCTION.—Amounts col-
4 lected under clause (i) shall not be counted
5 against the total amount of coverage avail-
6 able under subparagraph (A).

7 “(C) REDUCTION FOR LATE ENROLL-
8 MENT.—For each month during a calendar
9 quarter in which an eligible low-income bene-
10 ficiary is not enrolled in a prescription drug as-
11 sistance card program offered by a prescription
12 drug card sponsor with a contract under this
13 section, the amount of assistance available
14 under subparagraph (A) shall be reduced by
15 \$50.

16 “(D) CREDITING OF UNUSED BENEFITS
17 TOWARD FUTURE YEARS.—The dollar amount
18 of coverage described in subparagraph (A) shall
19 be increased by any amount of coverage de-
20 scribed in such subparagraph that was not used
21 during the previous calendar year.

22 “(E) WAIVER TO ENSURE PROVISION OF
23 BENEFIT.—The Secretary may waive such re-
24 quirements of this section and section 1807 as
25 may be necessary to ensure that each eligible

1 low-income beneficiaries has access to the as-
2 sistence described in subparagraph (A).

3 “(3) ADDITIONAL DISCOUNTS.—A prescription
4 drug card sponsor with a contract under this section
5 shall provide each eligible low-income beneficiary en-
6 rolled in a prescription drug assistance program of-
7 fered by the sponsor with access to negotiated prices
8 that reflect a minimum average discount of at least
9 20 percent of the average wholesale price for pre-
10 scription drugs covered under that program.

11 “(4) ASSISTANCE CARDS.—Each prescription
12 drug card sponsor shall permit eligible low-income
13 beneficiaries enrolled in a prescription drug assist-
14 ance card program offered by such sponsor to use
15 the discount card issued under section 1807(e)(4) to
16 obtain benefits under the program.

17 “(5) APPLICATION OF FORMULARY RESTRIC-
18 TIONS.—A drug prescribed for an eligible low-income
19 beneficiary that would otherwise be a covered drug
20 under this section shall not be so considered under
21 a prescription drug assistance card program if the
22 program excludes the drug under a formulary and
23 such exclusion is not successfully resolved under
24 paragraph (4), (5), or (6) of subsection (c).

1 “(e) REQUIREMENTS FOR PRESCRIPTION DRUG
2 CARD SPONSORS THAT OFFER PRESCRIPTION DRUG AS-
3 SISTANCE CARD PROGRAMS.—

4 “(1) IN GENERAL.—Each prescription drug
5 card sponsor shall—

6 “(A) process claims made by eligible low-
7 income beneficiaries;

8 “(B) negotiate with brand name and ge-
9 neric prescription drug manufacturers and oth-
10 ers for low prices on prescription drugs;

11 “(C) track individual beneficiary expendi-
12 tures in a format and periodicity specified by
13 the Secretary; and

14 “(D) perform such other functions as the
15 Secretary may assign.

16 “(2) DATA EXCHANGES.—Each prescription
17 drug card sponsor shall receive data exchanges in a
18 format specified by the Secretary and shall maintain
19 real-time beneficiary files.

20 “(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL
21 PRICES FOR EQUIVALENT DRUGS.—The prescription
22 drug card sponsor offering the prescription drug as-
23 sistance card program shall provide that each phar-
24 macy or other dispenser that arranges for the dis-
25 pensing of a covered drug shall inform the eligible

1 low-income beneficiary at the time of purchase of the
2 drug of any differential between the price of the pre-
3 scribed drug to the enrollee and the price of the low-
4 est priced generic drug covered under the plan that
5 is therapeutically equivalent and bioequivalent and
6 available at such pharmacy or other dispenser.

7 “(f) SUBMISSION OF BIDS AND AWARDING OF CON-
8 TRACTS.—

9 “(1) SUBMISSION OF BIDS.—Each prescription
10 drug card sponsor that seeks to offer a prescription
11 drug assistance card program under this section
12 shall submit to the Secretary, at such time and in
13 such manner as the Secretary may specify, such in-
14 formation as the Secretary may require.

15 “(2) AWARDING OF CONTRACTS.—The Sec-
16 retary shall review the information submitted under
17 paragraph (1) and shall determine whether to award
18 a contract to the prescription drug card sponsor of-
19 fering the program to which such information re-
20 lates. The Secretary may not approve a program un-
21 less the program and prescription drug card sponsor
22 offering the program comply with the requirements
23 under this section.

24 “(3) NUMBER OF CONTRACTS.—There shall be
25 no limit on the number of prescription drug card

sponsors that may be awarded contracts under paragraph (2).

“(4) CONTRACT PROVISIONS.—

“(A) DURATION.—A contract awarded under paragraph (2) shall be for the lifetime of the program under this section.

“(B) WITHDRAWAL.—A prescription drug card sponsor that desires to terminate the contract awarded under paragraph (2) may terminate such contract without penalty if such sponsor gives notice—

“(i) to the Secretary 90 days prior to the termination of such contract; and

“(ii) to each eligible low-income beneficiary that is enrolled in a prescription drug assistance card program offered by such sponsor 60 days prior to such termination.

“(C) SERVICE AREA.—The service area under the contract shall be the same as the area served by the prescription drug card sponsor under section 1807.

“(5) SIMULTANEOUS APPROVAL OF DISCOUNT CARD AND ASSISTANCE PROGRAMS.—A prescription drug card sponsor may submit an application for en-

1 dorsement under section 1807 as part of the bid
 2 submitted under paragraph (1) and the Secretary
 3 may approve such application at the same time as
 4 the Secretary awards a contract under this section.

5 “(g) PAYMENTS TO PRESCRIPTION DRUG CARD
 6 SPONSORS.—

7 “(1) IN GENERAL.—The Secretary shall pay to
 8 each prescription drug card sponsor offering a pre-
 9 scription drug assistance card program in which an
 10 eligible low-income beneficiary is enrolled an amount
 11 equal to the amount agreed to by the Secretary and
 12 the sponsor in the contract awarded under sub-
 13 section (f)(2).

14 “(2) PAYMENT FROM PART B TRUST FUND.—
 15 The costs of providing benefits under this section
 16 shall be payable from the Federal Supplementary
 17 Medical Insurance Trust Fund established under
 18 section 1841.

19 “(h) ELIGIBILITY DETERMINATIONS MADE BY
 20 STATES; PRESUMPTIVE ELIGIBILITY.—States shall per-
 21 form the functions described in section 1935(a)(1).

22 “(i) APPROPRIATIONS.—There are appropriated from
 23 the Federal Supplementary Medical Insurance Trust
 24 Fund established under section 1841 such sums as may
 25 be necessary to carry out the program under this section.

“(j) DEFINITIONS.—In this section:

“(1) ELIGIBLE BENEFICIARY; NEGOTIATED PRICE; PRESCRIPTION DRUG.—The terms ‘eligible beneficiary’, ‘negotiated price’, and ‘prescription drug’ have the meanings given those terms in section 1807(i).

“(2) ELIGIBLE LOW-INCOME BENEFICIARY.—The term ‘eligible low-income beneficiary’ means an individual who—

“(A) is an eligible beneficiary (as defined in section 1807(i)); and

“(B) is described in clause (iii) or (iv) of section 1902(a)(10)(E) or in section 1905(p)(1).

“(3) PRESCRIPTION DRUG CARD SPONSOR.—The term ‘prescription drug card sponsor’ has the meaning given that term in section 1807(i), except that such sponsor shall also be an entity that the Secretary determines is—

“(A) is appropriate to provide eligible low-income beneficiaries with the benefits under a prescription drug assistance card program under this section; and

“(B) is able to manage the monetary assistance made available under subsection (d)(2);

1 “(C) agrees to submit to audits by the Sec-
2 retary; and

3 “(D) provides such other assurances as the
4 Secretary may require.

5 “(4) STATE.—The term ‘State’ has the mean-
6 ing given such term for purposes of title XIX.”.

7 (b) EXCLUSION OF PRICES FROM DETERMINATION
8 OF BEST PRICE.—Section 1927(c)(1)(C)(i) (42 U.S.C.
9 1396r-8(c)(1)(C)(i)) is amended—

10 (1) by striking “and” at the end of subclause
11 (III);

12 (2) by striking the period at the end of sub-
13 clause (IV) and inserting “; and”; and

14 (3) by adding at the end the following new sub-
15 clause:

16 “(V) any negotiated prices
17 charged under the medicare prescrip-
18 tion drug discount card endorsement
19 program under section 1807 or under
20 the transitional prescription drug as-
21 sistance card program for eligible low-
22 income beneficiaries under section
23 1807A.”.

24 (c) EXCLUSION OF PRESCRIPTION DRUG ASSIST-
25 ANCE CARD COSTS FROM DETERMINATION OF PART B

1 MONTHLY PREMIUM.—Section 1839(g) of the Social Se-
 2 curity Act (42 U.S.C. 1395r(g)) is amended—

3 (1) by striking “attributable to the application
 4 of section” and inserting “attributable to—

5 “(1) the application of section”;

6 (2) by striking the period and inserting “;
 7 and”; and

8 (3) by adding at the end the following new
 9 paragraph:

10 “(2) the prescription drug assistance card pro-
 11 gram under section 1807A.”.

12 (d) REGULATIONS.—

13 (1) AUTHORITY FOR INTERIM FINAL REGULA-
 14 TIONS.—The Secretary may promulgate initial regu-
 15 lations implementing sections 1807 and 1807A of
 16 the Social Security Act (as added by this section) in
 17 interim final form without prior opportunity for pub-
 18 lic comment.

19 (2) FINAL REGULATIONS.—A final regulation
 20 reflecting public comments must be published within
 21 1 year of the interim final regulation promulgated
 22 under paragraph (1).

23 (3) EXEMPTION FROM THE PAPERWORK RE-
 24 Duction ACT.—The promulgation of the regulations
 25 under this subsection and the administration the

1 programs established by sections 1807 and 1807A of
 2 the Social Security Act (as added by this section)
 3 shall be made without regard to chapter 35 of title
 4 44, United States Code (commonly known as the
 5 “Paperwork Reduction Act”).

6 (e) IMPLEMENTATION; TRANSITION.—

7 (1) IMPLEMENTATION.—The Secretary shall
 8 implement the amendments made by this section in
 9 a manner that discounts are available to eligible
 10 beneficiaries under section 1807 of the Social Secu-
 11 rity Act and assistance is available to eligible low-in-
 12 come beneficiaries under section 1807A of such Act
 13 not later than January 1, 2004.

14 (2) TRANSITION.—The Secretary shall provide
 15 for an appropriate transition and discontinuation of
 16 the programs under section 1807 and 1807A of the
 17 Social Security Act. Such transition and discontinu-
 18 ation shall ensure that such programs continue to
 19 operate until the date on which the first enrollment
 20 period under part D ends.

21 **Subtitle C—Standards for** 22 **Electronic Prescribing**

23 **SEC. 121. STANDARDS FOR ELECTRONIC PRESCRIBING.**

24 Title XI (42 U.S.C. 1301 et seq.) is amended by add-
 25 ing at the end the following new part:

1 “PART D—ELECTRONIC PRESCRIBING

2 “STANDARDS FOR ELECTRONIC PRESCRIBING

3 “SEC. 1180. (a) STANDARDS.—

4 “(1) DEVELOPMENT AND ADOPTION.—

5 “(A) IN GENERAL.—The Secretary shall
6 develop or adopt standards for transactions and
7 data elements for such transactions (in this sec-
8 tion referred to as ‘standards’) to enable the
9 electronic transmission of medication history,
10 eligibility, benefit, and other prescription infor-
11 mation.

12 “(B) CONSULTATION.—In developing and
13 adopting the standards under subparagraph
14 (A), the Secretary shall consult with representa-
15 tives of physicians, hospitals, pharmacists,
16 standard setting organizations, pharmacy ben-
17 efit managers, beneficiary information exchange
18 networks, technology experts, and representa-
19 tives of the Departments of Veterans Affairs
20 and Defense and other interested parties.

21 “(2) OBJECTIVE.—Any standards developed or
22 adopted under this part shall be consistent with the
23 objectives of improving—

24 “(A) patient safety; and

1 “(B) the quality of care provided to pa-
2 tients.

3 “(3) REQUIREMENTS.—Any standards devel-
4 oped or adopted under this part shall comply with
5 the following:

6 “(A) PATIENT MAY REQUEST A WRITTEN
7 PRESCRIPTION.—The standards provide that—

8 “(i) a prescription shall be written
9 and not transmitted electronically if the
10 patient makes such a request; and

11 “(ii) no additional charges may be im-
12 posed on the patient for making such a re-
13 quest.

14 “(B) PATIENT-SPECIFIC MEDICATION HIS-
15 TORY, ELIGIBILITY, BENEFIT, AND OTHER PRE-
16 SCRIPTION INFORMATION.—

17 “(i) IN GENERAL.—The standards
18 shall accommodate electronic transmittal of
19 patient-specific medication history, eligi-
20 bility, benefit, and other prescription infor-
21 mation among prescribing and dispensing
22 professionals at the point of care.

23 “(ii) REQUIRED INFORMATION.—The
24 information described in clause (i) shall in-
25 clude the following:

“(I) Information (to the extent available and feasible) on the drugs being prescribed for that patient and other information relating to the medication history of the patient that may be relevant to the appropriate prescription for that patient.

“(II) Cost-effective alternatives (if any) to the drug prescribed.

“(III) Information on eligibility and benefits, including the drugs included in the applicable formulary and any requirements for prior authorization.

“(IV) Information on potential interactions with drugs listed on the medication history, graded by severity of the potential interaction.

“(V) Other information to improve the quality of patient care and to reduce medical errors.

“(C) UNDUE BURDEN.—The standards shall be designed so that, to the extent practicable, the standards do not impose an undue

1 administrative burden on the practice of medi-
 2 cine, pharmacy, or other health professions.

3 “(D) COMPATIBILITY WITH ADMINISTRA-
 4 TIVE SIMPLIFICATION AND PRIVACY LAWS.—

5 The standards shall be—

6 “(i) consistent with the Federal regu-
 7 lations (concerning the privacy of individ-
 8 ually identifiable health information) pro-
 9 mulgated under section 264(c) of the
 10 Health Insurance Portability and Account-
 11 ability Act of 1996; and

12 “(ii) compatible with the standards
 13 adopted under part C.

14 “(4) TRANSFER OF INFORMATION.—The Sec-
 15 retary shall develop and adopt standards for trans-
 16 ferring among prescribing and insurance entities and
 17 other necessary entities appropriate standard data
 18 elements needed for the electronic exchange of medi-
 19 cation history, eligibility, benefit, and other prescrip-
 20 tion drug information and other health information
 21 determined appropriate in compliance with the
 22 standards adopted or modified under this part.

23 “(b) TIMETABLE FOR ADOPTION OF STANDARDS.—

24 “(1) IN GENERAL.—The Secretary shall adopt
 25 the standards under this part by January 1, 2006.

“(2) ADDITIONS AND MODIFICATIONS TO STANDARDS.—The Secretary shall, in consultation with appropriate representatives of interested parties, review the standards developed or adopted under this part and adopt modifications to the standards (including additions to the standards), as determined appropriate. Any addition or modification to such standards shall be completed in a manner which minimizes the disruption and cost of compliance. *2011 update for prescribing* 01

“(c) COMPLIANCE WITH STANDARDS.—

“(1) REQUIREMENT FOR ALL INDIVIDUALS AND ENTITIES THAT TRANSMIT OR RECEIVE PRESCRIPTIONS ELECTRONICALLY.— *2011 update for prescribing* 01

“(A) IN GENERAL.—Individuals or entities that transmit or receive prescriptions electronically shall comply with the standards adopted or modified under this part.

“(B) RELATION TO STATE LAWS.—The standards adopted or modified under this part shall supersede any State law or regulations pertaining to the electronic transmission of medication history, eligibility, benefit and prescription information. *2011 update for prescribing* 01

“(2) TIMETABLE FOR COMPLIANCE.—

1 “(A) INITIAL COMPLIANCE.—

2 “(i) IN GENERAL.—Not later than 24
3 months after the date on which an initial
4 standard is adopted under this part, each
5 individual or entity to whom the standard
6 applies shall comply with the standard.

7 “(ii) SPECIAL RULE FOR SMALL
8 HEALTH PLANS.—In the case of a small
9 health plan, as defined by the Secretary for
10 purposes of section 1175(b)(1)(B), clause
11 (i) shall be applied by substituting ‘36
12 months’ for ‘24 months’.

13 “(d) CONSULTATION WITH ATTORNEY GENERAL.—
14 The Secretary shall consult with the Attorney General be-
15 fore developing, adopting, or modifying a standard under
16 this part to ensure that the standard accommodates secure
17 electronic transmission of prescriptions for controlled sub-
18 stances in a manner that minimizes the possibility of viola-
19 tions under the Comprehensive Drug Abuse Prevention
20 and Control Act of 1970 and related Federal laws.

21 “(e) NO REQUIREMENT TO TRANSMIT OR RECEIVE
22 PRESCRIPTIONS ELECTRONICALLY.—Nothing in this part
23 shall be construed to require an individual or entity to
24 transmit or receive prescriptions electronically.

1 "GRANTS TO HEALTH CARE PROVIDERS TO IMPLEMENT
2 ELECTRONIC PRESCRIPTION PROGRAMS

3 "SEC. 1180A. (a) IN GENERAL.—The Secretary is
4 authorized to make grants to health care providers for the
5 purpose of assisting such entities to implement electronic
6 prescription programs that comply with the standards
7 adopted or modified under this part.

8 "(b) APPLICATION.—No grant may be made under
9 this section except pursuant to a grant application that
10 is submitted in a time, manner, and form approved by the
11 Secretary.

12 "(c) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated for each of fiscal years
14 2006, 2007, and 2008, such sums as may be necessary
15 to carry out this section."

16 **Subtitle D—Other Provisions**

17 **SEC. 131. ADDITIONAL REQUIREMENTS FOR ANNUAL FI-**
18 **NANCIAL REPORT AND OVERSIGHT ON MEDI-**
19 **CARE PROGRAM.**

20 (a) IN GENERAL.—Section 1817 (42 U.S.C. 1395i)
21 is amended by adding at the end the following new sub-
22 section:

23 "(1) COMBINED REPORT ON OPERATION AND STATUS
24 OF THE TRUST FUND AND THE FEDERAL SUPPLE-
25 MENTARY MEDICAL INSURANCE TRUST FUND (INCLUD-

ING THE PRESCRIPTION DRUG ACCOUNT).—In addition to the duty of the Board of Trustees to report to Congress under subsection (b), on the date the Board submits the report required under subsection (b)(2), the Board shall submit to Congress a report on the operation and status of the Trust Fund and the Federal Supplementary Medical Insurance Trust Fund established under section 1841 (including the Prescription Drug Account within such Trust Fund), in this subsection referred to as the ‘Trust Funds’. Such report shall include the following information:

“(1) OVERALL SPENDING FROM THE GENERAL FUND OF THE TREASURY.—A statement of total amounts obligated during the preceding fiscal year from the General Revenues of the Treasury to the Trust Funds, separately stated in terms of the total amount and in terms of the percentage such amount bears to all other amounts obligated from such General Revenues during such fiscal year, for each of the following amounts:

“(A) MEDICARE BENEFITS.—The amount expended for payment of benefits covered under this title.

“(B) ADMINISTRATIVE AND OTHER EXPENSES.—The amount expended for payments

not related to the benefits described in subparagraph (A).

“(2) HISTORICAL OVERVIEW OF SPENDING.—

From the date of the inception of the program of insurance under this title through the fiscal year involved, a statement of the total amounts referred to in paragraph (1), separately stated for the amounts described in subparagraphs (A) and (B) of such paragraph.

“(3) 10-YEAR AND 50-YEAR PROJECTIONS.—An

estimate of total amounts referred to in paragraph (1), separately stated for the amounts described in subparagraphs (A) and (B) of such paragraph, required to be obligated for payment for benefits covered under this title for each of the 10 fiscal years succeeding the fiscal year involved and for the 50-year period beginning with the succeeding fiscal year.

“(4) RELATION TO OTHER MEASURES OF

GROWTH.—A comparison of the rate of growth of the total amounts referred to in paragraph (1), separately stated for the amounts described in subparagraphs (A) and (B) of such paragraph, to the rate of growth for the same period in—

“(A) the gross domestic product;

1 “(B) health insurance costs in the private
2 sector;

3 “(C) employment-based health insurance
4 costs in the public and private sectors; and

5 “(D) other areas as determined appro-
6 priate by the Board of Trustees.”.

7 (b) EFFECTIVE DATE.—The amendment made by
8 subsection (a) shall apply with respect to fiscal years be-
9 ginning on or after the date of enactment of this Act.

10 (c) CONGRESSIONAL HEARINGS.—It is the sense of
11 Congress that the committees of jurisdiction of Congress
12 shall hold hearings on the reports submitted under section
13 1817(l) of the Social Security Act (as added by subsection
14 (a)).

15 **SEC. 132. TRUSTEES’ REPORT ON MEDICARE’S UNFUNDED**
16 **OBLIGATIONS.**

17 (a) REPORT.—The report submitted under sections
18 1817(b)(2) and 1841(b)(2) of the Social Security Act (42
19 U.S.C. 1395i(b)(2) and 1395t(b)(2)) during 2004 shall in-
20 clude an analysis of the total amount of the unfunded obli-
21 gations of the Medicare program under title XVIII of the
22 Social Security Act.

23 (b) MATTERS ANALYZED.—The analysis described in
24 subsection (A) shall compare the long-term obligations of
25 the Medicare program to the dedicated funding sources

1 for that program (other than general revenue transfers),
 2 including the combined obligations of the Federal Hospital
 3 Insurance Trust Fund established under section 1817 of
 4 such Act (42 U.S.C. 1395i) and the Federal Supple-
 5 mentary Medical Insurance Trust Fund established under
 6 section 1841 of such Act (42 U.S.C. 1395t).

7 **SEC. 133. PHARMACY BENEFIT MANAGERS TRANSPARENCY**
 8 **REQUIREMENTS.**

9 Subpart 3 of part D of title XVIII of the Social Secu-
 10 rity Act (as added by section 101) is amended by adding
 11 at the end the following new section:

12 “PHARMACY BENEFIT MANAGERS TRANSPARENCY
 13 REQUIREMENTS

14 “SEC. 1860D–27. (a) PROHIBITION.—

15 “(1) IN GENERAL.—Notwithstanding any other
 16 provision of law, an eligible entity offering a Medi-
 17 care Prescription Drug plan under this part or a
 18 MedicareAdvantage organization offering a
 19 MedicareAdvantage plan under part C shall not
 20 enter into a contract with any pharmacy benefit
 21 manager (in this section referred to as a ‘PBM’)
 22 that is owned by a pharmaceutical manufacturing
 23 company.

24 “(2) PROVISION OF INFORMATION.—A PBM
 25 that manages prescription drug coverage under this
 26 part or part C shall provide the following informa-

tion, on an annual basis, to the Assistant Attorney General for Antitrust of the Department of Justice and the Inspector General of the Health and Human Services Department:

“(A) The aggregate amount of any and all rebates, discounts, administrative fees, promotional allowances, and other payments received or recovered from each pharmaceutical manufacturer.

“(B) The amount of payments received or recovered from each pharmaceutical manufacturer for each of the top 50 drugs as measured by volume (as determined by the Secretary).

“(C) The percentage differential between the price the PBM pays pharmacies for a drug described in subparagraph (B) and the price the PBM charges a Medicare Prescription Drug Plan or a MedicareAdvantage organization for such drug.

“(b) FAILURE TO DISCLOSE.—

“(1) CIVIL PENALTY.—Any PBM that fails to comply with subsection (a) shall be liable for a civil penalty as determined appropriate through regulations promulgated by the Attorney General. Such

penalty may be recovered in a civil action brought by the United States.

“(2) COMPLIANCE AND EQUITABLE RELIEF.—If any PBM fails to comply with subsection (a), the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General.

“(c) DISCLOSURE EXEMPTION.—Any information filed with the Assistant Attorney General under subsection (a)(2) shall be exempt from disclosure under section 552 of title 5, and no such information may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of Congress or to any duly authorized committee or subcommittee of the Congress.”.

SEC. 134. OFFICE OF THE MEDICARE BENEFICIARY ADVOCATE.

(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall establish within the Department of Health and Human Services, an Office of the Medicare Beneficiary Advocate (in this section referred to as the “Office”).

1 (b) DUTIES.—The Office shall carry out the following
2 activities:

3 (1) Establishing a toll-free telephone number
4 for medicare beneficiaries to use to obtain informa-
5 tion on the medicare program, and particularly with
6 respect to the benefits provided under part D of title
7 XVIII of the Social Security Act and the Medicare
8 Prescription Drug plans and MedicareAdvantage
9 plans offering such benefits. The Office shall ensure
10 that the toll-free telephone number accommodates
11 beneficiaries with disabilities and limited-English
12 proficiency.

13 (2) Establishing an Internet website with easily
14 accessible information regarding Medicare Prescrip-
15 tion Drug plans and MedicareAdvantage plans and
16 the benefits offered under such plans. The website
17 shall—

18 (A) be updated regularly to reflect changes
19 in services and benefits, including with respect
20 to the plans offered in a region and the associ-
21 ated monthly premiums, benefits offered,
22 formularies, and contact information for such
23 plans, and to ensure that there are no broken
24 links or errors;

(B) have printer-friendly, downloadable fact sheets on the medicare coverage options and benefits;

(C) be easy to navigate, with large print and easily recognizable links; and

(D) provide links to the websites of the eligible entities participating in part D of title XVIII.

(3) Providing regional publications to medicare beneficiaries that include regional contacts for information, and that inform the beneficiaries of the prescription drug benefit options under title XVIII of the Social Security Act, including with respect to—

(A) monthly premiums;

(B) formularies; and

(C) the scope of the benefits offered.

(4) Conducting outreach to medicare beneficiaries to inform the beneficiaries of the medicare coverage options and benefits under parts A, B, C, and D of title XVIII of the Social Security Act.

(5) Working with local benefits administrators, ombudsmen, local benefits specialists, and advocacy groups to ensure that medicare beneficiaries are aware of the medicare coverage options and benefits

under parts A, B, C, and D of title XVIII of the Social Security Act.

(c) FUNDING.—

(1) ESTABLISHMENT.—Of the amounts authorized to be appropriated under the Secretary's discretion for administrative expenditures, \$2,000,000 may be used to establish the Office in accordance with this section.

(2) OPERATION.—With respect to each fiscal year occurring after the fiscal year in which the Office is established under this section, the Secretary may use, out of amounts authorized to be appropriated under the Secretary's discretion for administrative expenditures for such fiscal year, such sums as may be necessary to operate the Office in that fiscal year.

TITLE II— MEDICAREADVANTAGE Subtitle A—MedicareAdvantage Competition

SEC. 201. ELIGIBILITY, ELECTION, AND ENROLLMENT.

Section 1851 (42 U.S.C. 1395w-21) is amended to read as follows:

“ELIGIBILITY, ELECTION, AND ENROLLMENT

“SEC. 1851. (a) CHOICE OF MEDICARE BENEFITS THROUGH MEDICAREADVANTAGE PLANS.—

“(1) IN GENERAL.—Subject to the provisions of this section, each MedicareAdvantage eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits under this title—

“(A) through—

“(i) the original Medicare fee-for-service program under parts A and B; and

“(ii) the voluntary prescription drug delivery program under part D; or

“(B) through enrollment in a MedicareAdvantage plan under this part.

“(2) TYPES OF MEDICAREADVANTAGE PLANS THAT MAY BE AVAILABLE.—A MedicareAdvantage plan may be any of the following types of plans of health insurance: ~~Part C~~

“(A) COORDINATED CARE PLANS.—Coordinated care plans which provide health care services, including health maintenance organization plans (with or without point of service options) and plans offered by provider-sponsored organizations (as defined in section 1855(d)).

“(B) COMBINATION OF MSA PLAN AND CONTRIBUTIONS TO MEDICAREADVANTAGE MSA.—An MSA plan, as defined in section 1859(b)(3), and a contribution into a

1 MedicareAdvantage medical savings account
2 (MSA).

3 “(C) PRIVATE FEE-FOR-SERVICE PLANS.—
4 A MedicareAdvantage private fee-for-service
5 plan, as defined in section 1859(b)(2).

6 “(3) MEDICAREADVANTAGE ELIGIBLE INDIVIDUAL.—

7
8 “(A) IN GENERAL.—Subject to subpara-
9 graph (B), in this title, the term
10 ‘MedicareAdvantage eligible individual’ means
11 an individual who is entitled to (or enrolled for)
12 benefits under part A, enrolled under part B,
13 and enrolled under part D.

14 “(B) SPECIAL RULE FOR END-STAGE
15 RENAL DISEASE.—Such term shall not include
16 an individual medically determined to have end-
17 stage renal disease, except that—

18 “(i) an individual who develops end-
19 stage renal disease while enrolled in a
20 Medicare+Choice or a MedicareAdvantage
21 plan may continue to be enrolled in that
22 plan; and

23 “(ii) in the case of such an individual
24 who is enrolled in a Medicare+Choice plan
25 or a MedicareAdvantage plan under clause

and if (i) (or subsequently under this clause), if
 and the enrollment is discontinued under cir-
 cumstances described in section
 1851(e)(4)(A), then the individual will be
 treated as a 'MedicareAdvantage eligible
 individual' for purposes of electing to con-
 tinue enrollment in another
 MedicareAdvantage plan.

“(b) SPECIAL RULES.— ~~section 1851(e)(4)(A)~~

“(1) RESIDENCE REQUIREMENT.—

“(A) IN GENERAL.—Except as the Sec-
 retary may otherwise provide and except as pro-
 vided in subparagraph (C), an individual is eli-
 gible to elect a MedicareAdvantage plan offered
 by a MedicareAdvantage organization only if
 the plan serves the geographic area in which
 the individual resides.

“(B) CONTINUATION OF ENROLLMENT
 PERMITTED.—Pursuant to rules specified by
 the Secretary, the Secretary shall provide that
 a plan may offer to all individuals residing in
 a geographic area the option to continue enroll-
 ment in the plan, notwithstanding that the indi-
 vidual no longer resides in the service area of
 the plan, so long as the plan provides that indi-

viduals exercising this option have, as part of the basic benefits described in section 1852(a)(1)(A), reasonable access within that geographic area to the full range of basic benefits, subject to reasonable cost-sharing liability in obtaining such benefits.

“(C) CONTINUATION OF ENROLLMENT PERMITTED WHERE SERVICE CHANGED.—Notwithstanding subparagraph (A) and in addition to subparagraph (B), if a MedicareAdvantage organization eliminates from its service area a MedicareAdvantage payment area that was previously within its service area, the organization may elect to offer individuals residing in all or portions of the affected area who would otherwise be ineligible to continue enrollment the option to continue enrollment in a MedicareAdvantage plan it offers so long as—

“(i) the enrollee agrees to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively at facilities designated by the organization within the plan service area; and

1 “(ii) there is no other
2 MedicareAdvantage plan offered in the
3 area in which the enrollee resides at the
4 time of the organization’s election.

5 “(2) SPECIAL RULE FOR CERTAIN INDIVIDUALS
6 COVERED UNDER FEHBP OR ELIGIBLE FOR VET-
7 ERANS OR MILITARY HEALTH BENEFITS.—

8 “(A) FEHBP.—An individual who is en-
9 rolled in a health benefit plan under chapter 89
10 of title 5, United States Code, is not eligible to
11 enroll in an MSA plan until such time as the
12 Director of the Office of Management and
13 Budget certifies to the Secretary that the Office
14 of Personnel Management has adopted policies
15 which will ensure that the enrollment of such
16 individuals in such plans will not result in in-
17 creased expenditures for the Federal Govern-
18 ment for health benefit plans under such chap-
19 ter.

20 “(B) VA AND DOD.—The Secretary may
21 apply rules similar to the rules described in
22 subparagraph (A) in the case of individuals who
23 are eligible for health care benefits under chap-
24 ter 55 of title 10, United States Code, or under
25 chapter 17 of title 38 of such Code.

1 “(3) LIMITATION ON ELIGIBILITY OF QUALI-
 2 FIED MEDICARE BENEFICIARIES AND OTHER MED-
 3 ICAID BENEFICIARIES TO ENROLL IN AN MSA
 4 PLAN.—An individual who is a qualified medicare
 5 beneficiary (as defined in section 1905(p)(1)), a
 6 qualified disabled and working individual (described
 7 in section 1905(s)), an individual described in sec-
 8 tion 1902(a)(10)(E)(iii), or otherwise entitled to
 9 medicare cost-sharing under a State plan under title
 10 XIX is not eligible to enroll in an MSA plan.

11 “(4) COVERAGE UNDER MSA PLANS ON A DEM-
 12 ONSTRATION BASIS.—

13 “(A) IN GENERAL.—An individual is not
 14 eligible to enroll in an MSA plan under this
 15 part—

16 “(i) on or after January 1, 2004, un-
 17 less the enrollment is the continuation of
 18 such an enrollment in effect as of such
 19 date; or

20 “(ii) as of any date if the number of
 21 such individuals so enrolled as of such date
 22 has reached 390,000.

23 Under rules established by the Secretary, an in-
 24 dividual is not eligible to enroll (or continue en-
 25 rollment) in an MSA plan for a year unless the

individual provides assurances satisfactory to the Secretary that the individual will reside in the United States for at least 183 days during the year.

“(B) EVALUATION.—The Secretary shall regularly evaluate the impact of permitting enrollment in MSA plans under this part on selection (including adverse selection), use of preventive care, access to care, and the financial status of the Trust Funds under this title.

“(C) REPORTS.—The Secretary shall submit to Congress periodic reports on the numbers of individuals enrolled in such plans and on the evaluation being conducted under subparagraph (B).

“(c) PROCESS FOR EXERCISING CHOICE.—

“(1) IN GENERAL.—The Secretary shall establish a process through which elections described in subsection (a) are made and changed, including the form and manner in which such elections are made and changed. Such elections shall be made or changed only during coverage election periods specified under subsection (e) and shall become effective as provided in subsection (f).

1 “(2) COORDINATION THROUGH
2 MEDICAREADVANTAGE ORGANIZATIONS.—

3 “(A) ENROLLMENT.—Such process shall
4 permit an individual who wishes to elect a
5 MedicareAdvantage plan offered by a
6 MedicareAdvantage organization to make such
7 election through the filing of an appropriate
8 election form with the organization.

9 “(B) DISENROLLMENT.—Such process
10 shall permit an individual, who has elected a
11 MedicareAdvantage plan offered by a
12 MedicareAdvantage organization and who wish-
13 es to terminate such election, to terminate such
14 election through the filing of an appropriate
15 election form with the organization.

16 “(3) DEFAULT.—

17 “(A) INITIAL ELECTION.—

18 “(i) IN GENERAL.—Subject to clause
19 (ii), an individual who fails to make an
20 election during an initial election period
21 under subsection (e)(1) is deemed to have
22 chosen the original medicare fee-for-service
23 program option.

24 “(ii) SEAMLESS CONTINUATION OF
25 COVERAGE.—The Secretary may establish

1 procedures under which an individual who
2 is enrolled in a Medicare+Choice plan or
3 another health plan (other than a
4 MedicareAdvantage plan) offered by a
5 MedicareAdvantage organization at the
6 time of the initial election period and who
7 fails to elect to receive coverage other than
8 through the organization is deemed to have
9 elected the MedicareAdvantage plan of-
10 fered by the organization (or, if the organi-
11 zation offers more than 1 such plan, such
12 plan or plans as the Secretary identifies
13 under such procedures).

14 “(B) CONTINUING PERIODS.—An indi-
15 vidual who has made (or is deemed to have
16 made) an election under this section is consid-
17 ered to have continued to make such election
18 until such time as—

19 “(i) the individual changes the elec-
20 tion under this section; or

21 “(ii) the MedicareAdvantage plan with
22 respect to which such election is in effect
23 is discontinued or, subject to subsection
24 (b)(1)(B), no longer serves the area in
25 which the individual resides.

1 “(d) PROVIDING INFORMATION TO PROMOTE IN-
2 FORMED CHOICE.—

3 “(1) IN GENERAL.—The Secretary shall provide
4 for activities under this subsection to broadly dis-
5 seminate information to medicare beneficiaries (and
6 prospective medicare beneficiaries) on the coverage
7 options provided under this section in order to pro-
8 mote an active, informed selection among such op-
9 tions.

10 “(2) PROVISION OF NOTICE.—

11 “(A) OPEN SEASON NOTIFICATION.—At
12 least 15 days before the beginning of each an-
13 nual, coordinated election period (as defined in
14 subsection (e)(3)(B)), the Secretary shall mail
15 to each MedicareAdvantage eligible individual
16 residing in an area the following:

17 “(i) GENERAL INFORMATION.—The
18 general information described in paragraph
19 (3).

20 “(ii) LIST OF PLANS AND COMPARI-
21 SON OF PLAN OPTIONS.—A list identifying
22 the MedicareAdvantage plans that are (or
23 will be) available to residents of the area
24 and information described in paragraph
25 (4) concerning such plans. Such informa-

section shall be presented in a comparative form.

“(iii) ADDITIONAL INFORMATION.—

Any other information that the Secretary determines will assist the individual in making the election under this section.

The mailing of such information shall be coordinated, to the extent practicable, with the mailing of any annual notice under section 1804.

“(B) NOTIFICATION TO NEWLY ELIGIBLE MEDICAREADVANTAGE ELIGIBLE INDIVIDUALS.—To the extent practicable, the Secretary shall, not later than 30 days before the beginning of the initial MedicareAdvantage enrollment period for an individual described in subsection (e)(1), mail to the individual the information described in subparagraph (A).

“(C) FORM.—The information disseminated under this paragraph shall be written and formatted using language that is easily understandable by medicare beneficiaries.

“(D) PERIODIC UPDATING.—The information described in subparagraph (A) shall be updated on at least an annual basis to reflect changes in the availability of

Medicare Advantage plans, the benefits under such plans, and the Medicare Advantage monthly basic beneficiary premium, Medicare Advantage monthly beneficiary premium for enhanced medical benefits, and Medicare Advantage monthly beneficiary obligation for qualified prescription drug coverage for such plans.

“(3) GENERAL INFORMATION.—General information under this paragraph, with respect to coverage under this part during a year, shall include the following:

“(A) BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—A general description of the benefits covered under parts A and B of the original Medicare fee-for-service program, including—

“(i) covered items and services;

“(ii) beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts; and

“(iii) any beneficiary liability for balance billing.

“(B) CATASTROPHIC COVERAGE AND COMBINED DEDUCTIBLE.—A description of the cat-

1 astrophic coverage and unified deductible appli-
2 cable under the plan. ~~For MAFFC.~~

3 “(C) OUTPATIENT PRESCRIPTION DRUG
4 COVERAGE BENEFITS.—The information re-
5 quired under section 1860D–4 with respect to
6 coverage for prescription drugs under the plan.

7 “(D) ELECTION PROCEDURES.—Informa-
8 tion and instructions on how to exercise election
9 options under this section.

10 “(E) RIGHTS.—A general description of
11 procedural rights (including grievance and ap-
12 peals procedures) of beneficiaries under the
13 original medicare fee-for-service program (in-
14 cluding such rights under part D) and the
15 Medicare Advantage program and the right to
16 be protected against discrimination based on
17 health status-related factors under section
18 1852(b). 3

19 “(F) INFORMATION ON MEDIGAP AND
20 MEDICARE SELECT.—A general description of
21 the benefits, enrollment rights, and other re-
22 quirements applicable to medicare supplemental
23 policies under section 1882 and provisions relat-
24 ing to medicare select policies described in sec-
25 tion 1882(t).

1 “(G) POTENTIAL FOR CONTRACT TERMI-
 2 NATION.—The fact that a MedicareAdvantage
 3 organization may terminate its contract, refuse
 4 to renew its contract, or reduce the service area
 5 included in its contract, under this part, and
 6 the effect of such a termination, nonrenewal, or
 7 service area reduction may have on individuals
 8 enrolled with the MedicareAdvantage plan
 9 under this part.

10 “(4) INFORMATION COMPARING PLAN OP-
 11 TIONS.—Information under this paragraph, with re-
 12 spect to a MedicareAdvantage plan for a year, shall
 13 include the following:

14 “(A) BENEFITS.—The benefits covered
 15 under the plan, including the following:

16 “(i) Covered items and services be-
 17 yond those provided under the original
 18 medicare fee-for-service program option.

19 “(ii) Beneficiary cost-sharing for any
 20 items and services described in clause (i)
 21 and paragraph (3)(A)(i), including infor-
 22 mation on the unified deductible under sec-
 23 tion 1852(a)(1)(C).

1 “(iii) The maximum limitations on
2 out-of-pocket expenses under section
3 1852(a)(1)(C).”

4 “(iv) In the case of an MSA plan, dif-
5 ferences in cost-sharing, premiums, and
6 balance billing under such a plan compared
7 to under other MedicareAdvantage plans.

8 “(v) In the case of a
9 MedicareAdvantage private fee-for-service
10 plan, differences in cost-sharing, pre-
11 miums, and balance billing under such a
12 plan compared to under other
13 MedicareAdvantage plans.

14 “(vi) The extent to which an enrollee
15 may obtain benefits through out-of-net-
16 work health care providers.

17 “(vii) The extent to which an enrollee
18 may select among in-network providers and
19 the types of providers participating in the
20 plan’s network.

21 “(viii) The organization’s coverage of
22 emergency and urgently needed care.

23 “(ix) The comparative information de-
24 scribed in section 1860D-4(b)(2) relating

1 to prescription drug coverage under the
2 plan.

3 “(B) PREMIUMS.—

4 “(i) IN GENERAL.—The
5 MedicareAdvantage monthly basic bene-
6 ficiary premium and MedicareAdvantage
7 monthly beneficiary premium for enhanced
8 medical benefits, if any, for the plan or, in
9 the case of an MSA plan, the
10 MedicareAdvantage monthly MSA pre-
11 mium.

12 “(ii) REDUCTIONS.—The reduction in
13 part B premiums, if any.

14 “(iii) NATURE OF THE PREMIUM FOR
15 ENHANCED MEDICAL BENEFITS.—Whether
16 the MedicareAdvantage monthly premium
17 for enhanced benefits is optional or manda-
18 tory.

19 “(C) SERVICE AREA.—The service area of
20 the plan.

21 “(D) QUALITY AND PERFORMANCE.—Plan
22 quality and performance indicators for the ben-
23 efits under the plan (and how such indicators
24 compare to quality and performance indicators
25 under the original medicare fee-for-service pro-

gram under parts A and B and under the voluntary prescription drug delivery program under part D in the area involved), including—

“(i) disenrollment rates for medicare enrollees electing to receive benefits through the plan for the previous 2 years (excluding disenrollment due to death or moving outside the plan’s service area);

“(ii) information on medicare enrollee satisfaction;

“(iii) information on health outcomes; and

“(iv) the recent record regarding compliance of the plan with requirements of this part (as determined by the Secretary).

“(5) MAINTAINING A TOLL-FREE NUMBER AND INTERNET SITE.—The Secretary shall maintain a toll-free number for inquiries regarding MedicareAdvantage options and the operation of this part in all areas in which MedicareAdvantage plans are offered and an Internet site through which individuals may electronically obtain information on such options and MedicareAdvantage plans.

1 “(6) USE OF NON-FEDERAL ENTITIES.—The
2 Secretary may enter into contracts with non-Federal
3 entities to carry out activities under this subsection.

4 “(7) PROVISION OF INFORMATION.—A
5 MedicareAdvantage organization shall provide the
6 Secretary with such information on the organization
7 and each MedicareAdvantage plan it offers as may
8 be required for the preparation of the information
9 referred to in paragraph (2)(A).

10 “(e) COVERAGE ELECTION PERIODS.—

11 “(1) INITIAL CHOICE UPON ELIGIBILITY TO
12 MAKE ELECTION IF MEDICAREADVANTAGE PLANS
13 AVAILABLE TO INDIVIDUAL.—If, at the time an indi-
14 vidual first becomes eligible to elect to receive bene-
15 fits under part B or D (whichever is later), there is
16 1 or more MedicareAdvantage plans offered in the
17 area in which the individual resides, the individual
18 shall make the election under this section during a
19 period specified by the Secretary such that if the in-
20 dividual elects a MedicareAdvantage plan during the
21 period, coverage under the plan becomes effective as
22 of the first date on which the individual may receive
23 such coverage.

“(2) OPEN ENROLLMENT AND DISENROLLMENT OPPORTUNITIES.—Subject to paragraph (5), the following rules shall apply:

“(A) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT THROUGH 2005.—At any time during the period beginning January 1, 1998, and ending on December 31, 2005, a Medicare+Choice eligible individual may change the election under subsection (a)(1).

“(B) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 6 MONTHS DURING 2006.—

~~“(i) IN GENERAL.~~—Subject to clause (ii) and subparagraph (D), at any time during the first 6 months of 2006, or, if the individual first becomes a MedicareAdvantage eligible individual during 2006, during the first 6 months during 2006 in which the individual is a MedicareAdvantage eligible individual, a MedicareAdvantage eligible individual may change the election under subsection (a)(1).

~~“(ii) LIMITATION OF 1 CHANGE.~~—An individual may exercise the right under

1 clause (i) only once. The limitation under
2 this clause shall not apply to changes in
3 elections effected during an annual, coordi-
4 nated election period under paragraph (3)
5 or during a special enrollment period under
6 the first sentence of paragraph (4).

7 “(C) CONTINUOUS OPEN ENROLLMENT
8 AND DISENROLLMENT FOR FIRST 3 MONTHS IN
9 SUBSEQUENT YEARS.—

10 “(i) IN GENERAL.—Subject to clause
11 (ii) and subparagraph (D), at any time
12 during the first 3 months of 2007 and
13 each subsequent year, or, if the individual
14 first becomes a MedicareAdvantage eligible
15 individual during 2007 or any subsequent
16 year, during the first 3 months of such
17 year in which the individual is a
18 MedicareAdvantage eligible individual, a
19 MedicareAdvantage eligible individual may
20 change the election under subsection
21 (a)(1).

22 “(ii) LIMITATION OF 1 CHANGE DUR-
23 ING OPEN ENROLLMENT PERIOD EACH
24 YEAR.—An individual may exercise the
25 right under clause (i) only once during the

applicable 3-month period described in such clause in each year. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

“(D) CONTINUOUS OPEN ENROLLMENT FOR INSTITUTIONALIZED INDIVIDUALS.—At any time during 2006 or any subsequent year, in the case of a MedicareAdvantage eligible individual who is institutionalized (as defined by the Secretary), the individual may elect under subsection (a)(1)—

~~for both~~“(i) to enroll in a MedicareAdvantage plan; or

“(ii) to change the MedicareAdvantage plan in which the individual is enrolled.

“(3) ANNUAL, COORDINATED ELECTION PERIOD.—

“(A) IN GENERAL.—Subject to paragraph (5), each individual who is eligible to make an election under this section may change such

1 election during an annual, coordinated election
2 period.

3 “(B) ANNUAL, COORDINATED ELECTION
4 PERIOD.—For purposes of this section, the
5 term ‘annual, coordinated election period’
6 means, with respect to a year before 2003 and
7 after 2006, the month of November before such
8 year and with respect to 2003, 2004, 2005, and
9 2006, the period beginning on November 15
10 and ending on December 31 of the year before
11 such year.

12 “(C) MEDICAREADVANTAGE HEALTH IN-
13 FORMATION FAIRS.—During the fall season of
14 each year (beginning with 2006), in conjunction
15 with the annual coordinated election period de-
16 fined in subparagraph (B), the Secretary shall
17 provide for a nationally coordinated educational
18 and publicity campaign to inform
19 MedicareAdvantage eligible individuals about
20 MedicareAdvantage plans and the election proc-
21 ess provided under this section.

22 “(D) SPECIAL INFORMATION CAMPAIGN IN
23 2005.—During the period beginning on Novem-
24 ber 15, 2005, and ending on December 31,
25 2005, the Secretary shall provide for an edu-

1 cational and publicity campaign to inform
 2 MedicareAdvantage eligible individuals about
 3 the availability of MedicareAdvantage plans,
 4 and eligible organizations with risk-sharing con-
 5 tracts under section 1876, offered in different
 6 areas and the election process provided under
 7 this section. *library drive on*

8 “(4) SPECIAL ELECTION PERIODS.—Effective
 9 on and after January 1, 2006, an individual may
 10 discontinue an election of a MedicareAdvantage plan
 11 offered by a MedicareAdvantage organization other
 12 than during an annual, coordinated election period
 13 and make a new election under this section if—

14 “(A)(i) the certification of the organization
 15 or plan under this part has been terminated, or
 16 the organization or plan has notified the indi-
 17 vidual of an impending termination of such cer-
 18 tification; or *20*

19 “(ii) the organization has terminated or
 20 otherwise discontinued providing the plan in the
 21 area in which the individual resides, or has no-
 22 tified the individual of an impending termi-
 23 nation or discontinuation of such plan; *25*

24 “(B) the individual is no longer eligible to
 25 elect the plan because of a change in the indi-

1 vidual's place of residence or other change in
2 circumstances (specified by the Secretary, but
3 not including termination of the individual's en-
4 rollment on the basis described in clause (i) or
5 (ii) of subsection (g)(3)(B));

6 “(C) the individual demonstrates (in ac-
7 cordance with guidelines established by the Sec-
8 retary) that—

9 “(i) the organization offering the plan
10 substantially violated a material provision
11 of the organization's contract under this
12 part in relation to the individual (including
13 the failure to provide an enrollee on a
14 timely basis medically necessary care for
15 which benefits are available under the plan
16 or the failure to provide such covered care
17 in accordance with applicable quality
18 standards); or

19 “(ii) the organization (or an agent or
20 other entity acting on the organization's
21 behalf) materially misrepresented the
22 plan's provisions in marketing the plan to
23 the individual; or

“(D) the individual meets such other exceptional conditions as the Secretary may provide.

Effective on and after January 1, 2006, an individual who, upon first becoming eligible for benefits under part A at age 65, enrolls in a MedicareAdvantage plan under this part, the individual may discontinue the election of such plan, and elect coverage under the original fee-for-service plan, at any time during the 12-month period beginning on the effective date of such enrollment.

“(5) SPECIAL RULES FOR MSA PLANS.—Notwithstanding the preceding provisions of this subsection, an individual—

“(A) may elect an MSA plan only during—

“(i) an initial open enrollment period described in paragraph (1);

“(ii) an annual, coordinated election period described in paragraph (3)(B); or

“(iii) the month of November 1998;

“(B) subject to subparagraph (C), may not discontinue an election of an MSA plan except during the periods described in clause (ii) or (iii) of subparagraph (A) and under the first sentence of paragraph (4); and

1 “(C) who elects an MSA plan during an
 2 annual, coordinated election period, and who
 3 never previously had elected such a plan, may
 4 revoke such election, in a manner determined
 5 by the Secretary, by not later than December
 6 15 following the date of the election.

7 “(6) OPEN ENROLLMENT PERIODS.—Subject to
 8 paragraph (5), a MedicareAdvantage organization—
 9 “(A) shall accept elections or changes to
 10 elections during the initial enrollment periods
 11 described in paragraph (1), during the period
 12 beginning on November 15, 2005, and ending
 13 on December 31, 2005, and during the annual,
 14 coordinated election period under paragraph (3)
 15 for each subsequent year, and during special
 16 election periods described in the first sentence
 17 of paragraph (4); and

18 “(B) may accept other changes to elections
 19 at such other times as the organization pro-
 20 vides.

21 “(f) EFFECTIVENESS OF ELECTIONS AND CHANGES
 22 OF ELECTIONS.—

23 “(1) DURING INITIAL COVERAGE ELECTION PE-
 24 RIOD.—An election of coverage made during the ini-
 25 tial coverage election period under subsection

(e)(1)(A) shall take effect upon the date the individual becomes entitled to (or enrolled for) benefits under part A, enrolled under part B, and enrolled under part D, except as the Secretary may provide (consistent with sections 1838 and 1860D-2)) in order to prevent retroactive coverage.

“(2) DURING CONTINUOUS OPEN ENROLLMENT PERIODS.—An election or change of coverage made under subsection (e)(2) shall take effect with the first day of the first calendar month following the date on which the election or change is made.

“(3) ANNUAL, COORDINATED ELECTION PERIOD.—An election or change of coverage made during an annual, coordinated election period (as defined in subsection (e)(3)(B)) in a year shall take effect as of the first day of the following year.

“(4) OTHER PERIODS.—An election or change of coverage made during any other period under subsection (e)(4) shall take effect in such manner as the Secretary provides in a manner consistent (to the extent practicable) with protecting continuity of health benefit coverage.

“(g) GUARANTEED ISSUE AND RENEWAL.—

“(1) IN GENERAL.—Except as provided in this subsection, a MedicareAdvantage organization shall

1 provide that at any time during which elections are
2 accepted under this section with respect to a
3 MedicareAdvantage plan offered by the organization,
4 the organization will accept without restrictions indi-
5 viduals who are eligible to make such election.

6 “(2) PRIORITY.—If the Secretary determines
7 that a MedicareAdvantage organization, in relation
8 to a MedicareAdvantage plan it offers, has a capac-
9 ity limit and the number of MedicareAdvantage eli-
10 gible individuals who elect the plan under this sec-
11 tion exceeds the capacity limit, the organization may
12 limit the election of individuals of the plan under
13 this section but only if priority in election is pro-
14 vided—

15 “(A) first to such individuals as have elect-
16 ed the plan at the time of the determination;
17 and

18 “(B) then to other such individuals in such
19 a manner that does not discriminate, on a basis
20 described in section 1852(b), among the individ-
21 uals (who seek to elect the plan).

22 The preceding sentence shall not apply if it would
23 result in the enrollment of enrollees substantially
24 nonrepresentative, as determined in accordance with

1 regulations of the Secretary, of the medicare popu-
 2 lation in the service area of the plan.

3 “(3) LIMITATION ON TERMINATION OF ELEC-
 4 TION.—

5 “(A) IN GENERAL.—Subject to subpara-
 6 graph (B), a MedicareAdvantage organization
 7 may not for any reason terminate the election
 8 of any individual under this section for a
 9 MedicareAdvantage plan it offers.

10 “(B) BASIS FOR TERMINATION OF ELEC-
 11 TION.—A MedicareAdvantage organization may
 12 terminate an individual’s election under this
 13 section with respect to a MedicareAdvantage
 14 plan it offers if—

15 “(i) any MedicareAdvantage monthly
 16 basic beneficiary premium,
 17 MedicareAdvantage monthly beneficiary
 18 obligation for qualified prescription drug
 19 coverage, or MedicareAdvantage monthly
 20 beneficiary premium for required or op-
 21 tional enhanced medical benefits required
 22 with respect to such plan are not paid on
 23 a timely basis (consistent with standards
 24 under section 1856 that provide for a

1 grace period for late payment of such pre-
2 miums);

3 “(ii) the individual has engaged in
4 disruptive behavior (as specified in such
5 standards); or

6 “(iii) the plan is terminated with re-
7 spect to all individuals under this part in
8 the area in which the individual resides.

9 “(C) CONSEQUENCE OF TERMINATION.—

10 “(i) TERMINATIONS FOR CAUSE.—
11 Any individual whose election is terminated
12 under clause (i) or (ii) of subparagraph
13 (B) is deemed to have elected to receive
14 benefits under the original medicare fee-
15 for-service program option.

16 “(ii) TERMINATION BASED ON PLAN
17 TERMINATION OR SERVICE AREA REDUC-
18 TION.—Any individual whose election is
19 terminated under subparagraph (B)(iii)
20 shall have a special election period under
21 subsection (e)(4)(A) in which to change
22 coverage to coverage under another
23 MedicareAdvantage plan. Such an indi-
24 vidual who fails to make an election during
25 such period is deemed to have chosen to

change coverage to the original medicare
fee-for-service program option.

“(D) ORGANIZATION OBLIGATION WITH
RESPECT TO ELECTION FORMS.—Pursuant to a
contract under section 1857858., each
MedicareAdvantage organization receiving an
election form under subsection (c)(2) shall
transmit to the Secretary (at such time and in
such manner as the Secretary may specify) a
copy of such form or such other information re-
specting the election as the Secretary may
specify.

“(h) APPROVAL OF MARKETING MATERIAL AND AP-
PLICATION FORMS.—

“(1) SUBMISSION.—No marketing material or
application form may be distributed by a
MedicareAdvantage organization to (or for the use
of) MedicareAdvantage eligible individuals unless—

“(A) at least 45 days (or 10 days in the
case described in paragraph (5)) before the date
of distribution the organization has submitted
the material or form to the Secretary for re-
view; and

“(B) the Secretary has not disapproved the
distribution of such material or form.

1 “(2) REVIEW.—The standards established
2 under section 1856 shall include guidelines for the
3 review of any material or form submitted and under
4 such guidelines the Secretary shall disapprove (or
5 later require the correction of) such material or form
6 if the material or form is materially inaccurate or
7 misleading or otherwise makes a material misrepre-
8 sentation.

9 “(3) DEEMED APPROVAL (1-STOP SHOPPING).—
10 In the case of material or form that is submitted
11 under paragraph (1)(A) to the Secretary or a re-
12 gional office of the Department of Health and
13 Human Services and the Secretary or the office has
14 not disapproved the distribution of marketing mate-
15 rial or form under paragraph (1)(B) with respect to
16 a MedicareAdvantage plan in an area, the Secretary
17 is deemed not to have disapproved such distribution
18 in all other areas covered by the plan and organiza-
19 tion except with regard to that portion of such mate-
20 rial or form that is specific only to an area involved.

21 “(4) PROHIBITION OF CERTAIN MARKETING
22 PRACTICES.—Each MedicareAdvantage organization
23 shall conform to fair marketing standards, in rela-
24 tion to MedicareAdvantage plans offered under this

part, included in the standards established under section 1856. Such standards—

“(A) shall not permit a MedicareAdvantage organization to provide for cash or other monetary rebates as an inducement for enrollment or otherwise (other than as an additional benefit described in section 1854(g)(1)(C)(i)); and

“(B) may include a prohibition against a MedicareAdvantage organization (or agent of such an organization) completing any portion of any election form used to carry out elections under this section on behalf of any individual.

“(5) SPECIAL TREATMENT OF MARKETING MATERIAL FOLLOWING MODEL MARKETING LANGUAGE.—In the case of marketing material of an organization that uses, without modification, proposed model language specified by the Secretary, the period specified in paragraph (1)(A) shall be reduced from 45 days to 10 days.

“(i) EFFECT OF ELECTION OF MEDICAREADVANTAGE PLAN OPTION.—

“(1) PAYMENTS TO ORGANIZATIONS.—Subject to sections 1852(a)(5), 1853(h), 1853(i), 1886(d)(11), and 1886(h)(3)(D), payments under a contract with a MedicareAdvantage organization

under section 1853(a) with respect to an individual electing a MedicareAdvantage plan offered by the organization shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under parts A, B, and D for items and services furnished to the individual.

“(2) ONLY ORGANIZATION ENTITLED TO PAYMENT.—Subject to sections 1853(f), 1853(h), 1853(i), 1857(f)(2), 1886(d)(11), and 1886(h)(3)(D), only the MedicareAdvantage organization shall be entitled to receive payments from the Secretary under this title for services furnished to the individual.”.

SEC. 202. BENEFITS AND BENEFICIARY PROTECTIONS.

Section 1852 (42 U.S.C. 1395w-22) is amended to read as follows:

“BENEFITS AND BENEFICIARY PROTECTIONS

“SEC. 1852. (a) BASIC BENEFITS.—

“(1) IN GENERAL.—Except as provided in section 1859(b)(3) for MSA plans, each MedicareAdvantage plan shall provide to members enrolled under this part, through providers and other persons that meet the applicable requirements of this title and part A of title XI—

“(A) those items and services (other than hospice care) for which benefits are available

under parts A and B to individuals residing in the area served by the plan;

“(B) except as provided in paragraph (2)(D), qualified prescription drug coverage under part D to individuals residing in the area served by the plan;

“(C) a maximum limitation on out-of-pocket expenses and a unified deductible; and

“(D) additional benefits required under section 1854(d)(1).

“(2) SATISFACTION OF REQUIREMENT.—

“(A) IN GENERAL.—A MedicareAdvantage plan (other than an MSA plan) offered by a MedicareAdvantage organization satisfies paragraph (1)(A), with respect to benefits for items and services furnished other than through a provider or other person that has a contract with the organization offering the plan, if the plan provides payment in an amount so that—

“(i) the sum of such payment amount and any cost-sharing provided for under the plan; is equal to at least

“(ii) the total dollar amount of payment for such items and services as would otherwise be authorized under parts A and

1 B (including any balance billing permitted
2 under such parts).

3 “(B) REFERENCE TO RELATED PROVI-
4 SIONS.—For provisions relating to—

5 “(i) limitations on balance billing
6 against MedicareAdvantage organizations
7 for noncontract providers, see sections
8 1852(k) and 1866(a)(1)(O); and

9 “(ii) limiting actuarial value of en-
10 rollee liability for covered benefits, see sec-
11 tion 1854(f).

12 “(C) ELECTION OF UNIFORM COVERAGE
13 POLICY.—In the case of a MedicareAdvantage
14 organization that offers a MedicareAdvantage
15 plan in an area in which more than 1 local cov-
16 erage policy is applied with respect to different
17 parts of the area, the organization may elect to
18 have the local coverage policy for the part of
19 the area that is most beneficial to
20 MedicareAdvantage enrollees (as identified by
21 the Secretary) apply with respect to all
22 MedicareAdvantage enrollees enrolled in the
23 plan.

24 “(D) SPECIAL RULE FOR PRIVATE FEE-
25 FOR-SERVICE PLANS.—

1 “(i) IN GENERAL.—A private fee-for-
2 service plan may elect not to provide quali-
3 fied prescription drug coverage under part
4 D to individuals residing in the area served
5 by the plan.

6 “(ii) AVAILABILITY OF DRUG COV-
7 ERAGE FOR ENROLLEES.—If a beneficiary
8 enrolls in a plan making the election de-
9 scribed in clause (i), the beneficiary may
10 enroll for drug coverage under part D with
11 an eligible entity under such part.

12 “(3) ENHANCED MEDICAL BENEFITS.—

13 “(A) BENEFITS INCLUDED SUBJECT TO
14 SECRETARY’S ~~CONSENT~~ APPROVAL.—Each
15 MedicareAdvantage organization may provide to
16 individuals enrolled under this part, other than
17 under an MSA plan (without affording those in-
18 dividuals an option to decline the coverage), en-
19 hanced medical benefits that the Secretary may
20 approve. The Secretary shall approve any such
21 enhanced medical benefits unless the Secretary
22 determines that including such enhanced med-
23 ical benefits would substantially discourage en-
24 rollment by MedicareAdvantage eligible individ-
25 uals with the organization.

1 “(B) AT ENROLLEES’ OPTION.—A
 2 MedicareAdvantage organization may not pro-
 3 vide, under an MSA plan, enhanced medical
 4 benefits that cover the deductible described in
 5 section 1859(b)(2)(B). In applying the previous
 6 sentence, health benefits described in section
 7 1882(u)(2)(B) shall not be treated as covering
 8 such deductible.

9 “(C) APPLICATION TO
 10 MEDICAREADVANTAGE PRIVATE FEE-FOR-SERV-
 11 ICE PLANS.—Nothing in this paragraph shall be
 12 construed as preventing a MedicareAdvantage
 13 private fee-for-service plan from offering en-
 14 hanced medical benefits that include payment
 15 for some or all of the balance billing amounts
 16 permitted consistent with section 1852(k) and
 17 coverage of additional services that the plan
 18 finds to be medically necessary.

19 “(D) RULE FOR APPROVAL OF MEDICAL
 20 AND PRESCRIPTION DRUG BENEFITS.—Notwith-
 21 standing the preceding provisions of this para-
 22 graph, the Secretary may not approve any en-
 23 hanced medical benefit that provides for the
 24 coverage of any prescription drug (other than
 25 that relating to prescription drugs covered

under the original medicare fee-for-service program option).

“(4) ORGANIZATION AS SECONDARY PAYER.—

Notwithstanding any other provision of law, a MedicareAdvantage organization may (in the case of the provision of items and services to an individual under a MedicareAdvantage plan under circumstances in which payment under this title is made secondary pursuant to section 1862(b)(2)) charge or authorize the provider of such services to charge, in accordance with the charges allowed under a law, plan, or policy described in such section—

“(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services; or

“(B) such individual to the extent that the individual has been paid under such law, plan, or policy for such services.

“(5) NATIONAL COVERAGE DETERMINATIONS AND LEGISLATIVE CHANGES IN BENEFITS.—If there is a national coverage determination or legislative change in benefits required to be provided under this part made in the period beginning on the date of an

1 announcement under section 1853(b) and ending on
2 the date of the next announcement under such sec-
3 tion and the Secretary projects that the determina-
4 tion will result in a significant change in the costs
5 to a MedicareAdvantage organization of providing
6 the benefits that are the subject of such national
7 coverage determination and that such change in
8 costs was not incorporated in the determination of
9 the benchmark amount announced under section
10 1853(b)(1)(A) at the beginning of such period, then,
11 unless otherwise required by law—

12 “(A) such determination or legislative
13 change in benefits shall not apply to contracts
14 under this part until the first contract year that
15 begins after the end of such period; and

16 “(B) if such coverage determination or leg-
17 islative change provides for coverage of addi-
18 tional benefits or coverage under additional cir-
19 cumstances, section 1851(i)(1) shall not apply
20 to payment for such additional benefits or bene-
21 fits provided under such additional cir-
22 cumstances until the first contract year that be-
23 gins after the end of such period.

24 The projection under the previous sentence shall be
25 based on an analysis by the Secretary of the actu-

1 arial costs associated with the coverage determina-
 2 tion or legislative change in benefits.

3 “(6) AUTHORITY TO PROHIBIT RISK SELEC-
 4 TION.—The Secretary shall have the authority to
 5 disapprove any MedicareAdvantage plan that the
 6 Secretary determines is designed to attract a popu-
 7 lation that is healthier than the average population
 8 residing in the service area of the plan.

9 “(7) UNIFIED DEDUCTIBLE DEFINED.—In this
 10 part, the term ‘unified deductible’ means an annual
 11 deductible amount that is applied in lieu of the inpa-
 12 tient hospital deductible under section 1813(b)(1)
 13 and the deductible under section 1833(b). Nothing
 14 in this part shall be construed as preventing a
 15 MedicareAdvantage organization from requiring co-
 16 insurance or a copayment for inpatient hospital serv-
 17 ices after the unified deductible is satisfied, subject
 18 to the limitation on enrollee liability under section
 19 1854(f).

20 “(b) ANTIDISCRIMINATION.— 1 on 2-dict 01

21 “(1) BENEFICIARIES.— 12

22 “(A) IN GENERAL.—A MedicareAdvantage
 23 organization may not deny, limit, or condition
 24 the coverage or provision of benefits under this
 25 part, for individuals permitted to be enrolled

1 with the organization under this part, based on
2 any health status-related factor described in
3 section 2702(a)(1) of the Public Health Service
4 Act.

5 “(B) CONSTRUCTION.—Except as provided
6 under section 1851(a)(3)(B), subparagraph (A)
7 shall not be construed as requiring a
8 MedicareAdvantage organization to enroll indi-
9 viduals who are determined to have end-stage
10 renal disease.

11 “(2) PROVIDERS.—A MedicareAdvantage orga-
12 nization shall not discriminate with respect to par-
13 ticipation, reimbursement, or indemnification as to
14 any provider who is acting within the scope of the
15 provider’s license or certification under applicable
16 State law, solely on the basis of such license or cer-
17 tification. This paragraph shall not be construed to
18 prohibit a plan from including providers only to the
19 extent necessary to meet the needs of the plan’s en-
20 rollees or from establishing any measure designed to
21 maintain quality and control costs consistent with
22 the responsibilities of the plan.

23 “(c) DISCLOSURE REQUIREMENTS.—

24 “(1) DETAILED DESCRIPTION OF PLAN PROVI-
25 SIONS.—A MedicareAdvantage organization shall

disclose, in clear, accurate, and standardized form to each enrollee with a MedicareAdvantage plan offered by the organization under this part at the time of enrollment and at least annually thereafter, the following information regarding such plan:

“(A) SERVICE AREA.—The plan’s service area.

“(B) BENEFITS.—Benefits offered under the plan, including information described section 1852(a)(1) (relating to benefits under the original medicare fee-for-service program option, the maximum limitation in out-of-pocket expenses and the unified deductible, and qualified prescription drug coverage under part D, respectively) and exclusions from coverage and, if it is an MSA plan, a comparison of benefits under such a plan with benefits under other MedicareAdvantage plans.

“(C) ACCESS.—The number, mix, and distribution of plan providers, out-of-network coverage (if any) provided by the plan, and any point-of-service option (including the MedicareAdvantage monthly beneficiary premium for enhanced medical benefits for such option).

1 “(D) OUT-OF-AREA COVERAGE.—Out-of-
2 area coverage provided by the plan.

3 “(E) EMERGENCY COVERAGE.—Coverage
4 of emergency services, including—

5 “(i) the appropriate use of emergency
6 services, including use of the 911 telephone
7 system or its local equivalent in emergency
8 situations and an explanation of what con-
9 stitutes an emergency situation;

10 “(ii) the process and procedures of the
11 plan for obtaining emergency services; and

12 “(iii) the locations of—

13 “(I) emergency departments; and

14 “(II) other settings, in which
15 plan physicians and hospitals provide
16 emergency services and post-stabiliza-
17 tion care.

18 “(F) ENHANCED MEDICAL BENEFITS.—
19 Enhanced medical benefits available from the
20 organization offering the plan, including—

21 “(i) whether the enhanced medical
22 benefits are optional;

23 “(ii) the enhanced medical benefits
24 covered; and

1 “(iii) the MedicareAdvantage monthly
2 beneficiary premium for enhanced medical
3 benefits.

4 “(G) PRIOR AUTHORIZATION RULES.—
5 Rules regarding prior authorization or other re-
6 view requirements that could result in non-
7 payment.

8 “(H) PLAN GRIEVANCE AND APPEALS PRO-
9 CEDURES.—All plan appeal or grievance rights
10 and procedures.

11 “(I) QUALITY ASSURANCE PROGRAM.—A
12 description of the organization’s quality assur-
13 ance program under subsection (e).

14 “(2) DISCLOSURE UPON REQUEST.—Upon re-
15 quest of a MedicareAdvantage eligible individual, a
16 MedicareAdvantage organization must provide the
17 following information to such individual:

18 “(A) The general coverage information and
19 general comparative plan information made
20 available under clauses (i) and (ii) of section
21 1851(d)(2)(A).

22 “(B) Information on procedures used by
23 the organization to control utilization of serv-
24 ices and expenditures.

1 “(C) Information on the number of griev-
2 ances, reconsiderations, and appeals and on the
3 disposition in the aggregate of such matters.

4 “(D) An overall summary description as to
5 the method of compensation of participating
6 physicians.

7 “(E) The information described in sub-
8 paragraphs (A) through (C) in relation to the
9 qualified prescription drug coverage provided by
10 the organization.

11 “(d) ACCESS TO SERVICES.—

12 “(1) IN GENERAL.—A MedicareAdvantage or-
13 ganization offering a MedicareAdvantage plan may
14 select the providers from whom the benefits under
15 the plan are provided so long as—

16 “(A) the organization makes such benefits
17 available and accessible to each individual elect-
18 ing the plan within the plan service area with
19 reasonable promptness and in a manner which
20 assures continuity in the provision of benefits;

21 “(B) when medically necessary the organi-
22 zation makes such benefits available and acces-
23 sible 24 hours a day and 7 days a week;

24 “(C) the plan provides for reimbursement
25 with respect to services which are covered under

subparagraphs (A) and (B) and which are provided to such an individual other than through the organization, if—

“(i) the services were not emergency services (as defined in paragraph (3)), but—

“(I) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition; and

“(II) it was not reasonable given the circumstances to obtain the services through the organization;

“(ii) the services were renal dialysis services and were provided other than through the organization because the individual was temporarily out of the plan’s service area; or

“(iii) the services are maintenance care or post-stabilization care covered under the guidelines established under paragraph (2);

“(D) the organization provides access to appropriate providers, including credentialed

1 specialists, for medically necessary treatment
2 and services; and

3 “(E) coverage is provided for emergency
4 services (as defined in paragraph (3)) without
5 regard to prior authorization or the emergency
6 care provider’s contractual relationship with the
7 organization.

8 “(2) GUIDELINES RESPECTING COORDINATION
9 OF POST-STABILIZATION CARE.—A
10 MedicareAdvantage plan shall comply with such
11 guidelines as the Secretary may prescribe relating to
12 promoting efficient and timely coordination of appro-
13 priate maintenance and post-stabilization care of an
14 enrollee after the enrollee has been determined to be
15 stable under section 1867.

16 “(3) DEFINITION OF EMERGENCY SERVICES.—
17 In this subsection—

18 “(A) IN GENERAL.—The term ‘emergency
19 services’ means, with respect to an individual
20 enrolled with an organization, covered inpatient
21 and outpatient services that—

22 “(i) are furnished by a provider that
23 is qualified to furnish such services under
24 this title; and

“(ii) are needed to evaluate or stabilize an emergency medical condition (as defined in subparagraph (B)).

“(B) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON.—The term ‘emergency medical condition’ means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

“(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

“(ii) serious impairment to bodily functions; or

“(iii) serious dysfunction of any bodily organ or part.

“(4) ASSURING ACCESS TO SERVICES IN MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS.—In addition to any other requirements under this part, in the case of a MedicareAdvantage private fee-for-service plan,

1 the organization offering the plan must dem-
2 onstrate to the Secretary that the organization
3 has sufficient number and range of health care
4 professionals and providers willing to provide
5 services under the terms of the plan. The Sec-
6 retary shall find that an organization has met
7 such requirement with respect to any category
8 of health care professional or provider if, with
9 respect to that category of provider—

10 “(A) the plan has established payment
11 rates for covered services furnished by that
12 category of provider that are not less than
13 the payment rates provided for under part
14 of A, B, or D for such services; or

15 “(B) the plan has contracts or agree-
16 ments (other than deemed contracts or
17 agreements under subsection (j)(6), with a
18 sufficient number and range of providers
19 within such category to provide covered
20 services under the terms of the plan,
21 or a combination of both. The previous sentence
22 shall not be construed as restricting the persons
23 from whom enrollees under such a plan may ob-
24 tain covered benefits, except that, if a plan en-
25 tirely meets such requirement with respect to a

category of health care professional or provider on the basis of subparagraph (B), it may provide for a higher beneficiary copayment in the case of health care professionals and providers of that category who do not have contracts or agreements (other than deemed contracts or agreements under subsection (j)(6)) to provide covered services under the terms of the plan.

“(e) QUALITY ASSURANCE PROGRAM.—

“(1) IN GENERAL.—Each MedicareAdvantage organization must have arrangements, consistent with any regulation, for an ongoing quality assurance program for health care services it provides to individuals enrolled with MedicareAdvantage plans of the organization.

“(2) ELEMENTS OF PROGRAM.—

“(A) IN GENERAL.—The quality assurance program of an organization with respect to a MedicareAdvantage plan (other than a MedicareAdvantage private fee-for-service plan or a nonnetwork MSA plan) it offers shall—

“(i) stress health outcomes and provide for the collection, analysis, and reporting of data (in accordance with a quality measurement system that the Secretary

- 1 recognizes) that will permit measurement
- 2 of outcomes and other indices of the qual-
- 3 ity of MedicareAdvantage plans and orga-
- 4 nizations;
- 5 “(ii) monitor and evaluate high vol-
- 6 ume and high risk services and the care of
- 7 acute and chronic conditions;
- 8 “(iii) provide access to disease man-
- 9 agement and chronic care services;
- 10 “(iv) provide access to preventive ben-
- 11 efits and information for enrollees on such
- 12 benefits;
- 13 “(v) evaluate the continuity and co-
- 14 ordination of care that enrollees receive;
- 15 “(vi) be evaluated on an ongoing basis
- 16 as to its effectiveness;
- 17 “(vii) include measures of consumer
- 18 satisfaction;
- 19 “(viii) provide the Secretary with such
- 20 access to information collected as may be
- 21 appropriate to monitor and ensure the
- 22 quality of care provided under this part;
- 23 “(ix) provide review by physicians and
- 24 other health care professionals of the proc-

ess followed in the provision of such health
care services;

“(x) provide for the establishment of
written protocols for utilization review,
based on current standards of medical
practice;

“(xi) have mechanisms to detect both
underutilization and overutilization of serv-
ices;

“(xii) after identifying areas for im-
provement, establish or alter practice pa-
rameters;

“(xiii) take action to improve quality
and assesses the effectiveness of such ac-
tion through systematic followup; and

“(xiv) make available information on
quality and outcomes measures to facilitate
beneficiary comparison and choice of
health coverage options (in such form and
on such quality and outcomes measures as
the Secretary determines to be appro-
priate).

Such program shall include a separate focus
(with respect to all the elements described in

1 this subparagraph) on racial and ethnic minori-
 2 ties.

3 ~~addition of~~ “(B) ELEMENTS OF PROGRAM FOR ORGA-
 4 ~~nizations~~ NIZATIONS OFFERING MEDICAREADVANTAGE
 5 PRIVATE FEE-FOR-SERVICE PLANS, AND NON-
 6 NETWORK MSA PLANS.—The quality assurance
 7 program of an organization with respect to a
 8 MedicareAdvantage private fee-for-service plan
 9 or a nonnetwork MSA plan it offers shall—

10 “(i) meet the requirements of clauses
 11 ~~of~~ (i) through (viii) of subparagraph (A); ~~and~~

12 “(ii) insofar as it provides for the es-
 13 ~~tab~~ tablishment of written protocols for utiliza-
 14 ~~tion~~ tion review, base such protocols on current
 15 standards of medical practice; and ~~and~~

16 ~~However, if~~ “(iii) have mechanisms to evaluate
 17 utilization of services and inform providers
 18 and enrollees of the results of such evalua-
 19 tion.

20 Such program shall include a separate focus
 21 (with respect to all the elements described in
 22 this subparagraph) on racial and ethnic minori-
 23 ties.

24 “(C) DEFINITION OF NONNETWORK MSA
 25 PLAN.—In this subsection, the term ‘nonnet-

work MSA plan' means an MSA plan offered by a MedicareAdvantage organization that does not provide benefits required to be provided by this part, in whole or in part, through a defined set of providers under contract, or under another arrangement, with the organization.

“(3) EXTERNAL REVIEW.—

“(A) *IN* GENERAL.—Each MedicareAdvantage organization shall, for each MedicareAdvantage plan it operates, have an agreement with an independent quality review and improvement organization approved by the Secretary to perform functions of the type described in paragraphs (4)(B) and (14) of section 1154(a) with respect to services furnished by MedicareAdvantage plans for which payment is made under this title. The previous sentence shall not apply to a MedicareAdvantage private fee-for-service plan or a nonnetwork MSA plan that does not employ utilization review.

“(B) NONDUPLICATION OF ACCREDITATION.—Except in the case of the review of quality complaints, and consistent with subparagraph (C), the Secretary shall ensure that the external review activities conducted under sub-

1 paragraph (A) are not duplicative of review ac-
2 tivities conducted as part of the accreditation
3 process.

4 “(C) WAIVER AUTHORITY.—The Secretary
5 may waive the requirement described in sub-
6 paragraph (A) in the case of an organization if
7 the Secretary determines that the organization
8 has consistently maintained an excellent record
9 of quality assurance and compliance with other
10 requirements under this part.

11 “(4) TREATMENT OF ACCREDITATION.—

12 “(A) IN GENERAL.—The Secretary shall
13 provide that a MedicareAdvantage organization
14 is deemed to meet all the requirements de-
15 scribed in any specific clause of subparagraph
16 (B) if the organization is accredited (and peri-
17 odically reaccredited) by a private accrediting
18 organization under a process that the Secretary
19 has determined assures that the accrediting or-
20 ganization applies and enforces standards that
21 meet or exceed the standards established under
22 section 1856 to carry out the requirements in
23 such clause.

“(B) REQUIREMENTS DESCRIBED.—The provisions described in this subparagraph are the following:

“(i) Paragraphs (1) and (2) of this subsection (relating to quality assurance programs).

“(ii) Subsection (b) (relating to anti-discrimination).

“(iii) Subsection (d) (relating to access to services).

“(iv) Subsection (h) (relating to confidentiality and accuracy of enrollee records).

“(v) Subsection (i) (relating to information on advance directives).

“(vi) Subsection (j) (relating to provider participation rules).

“(C) TIMELY ACTION ON APPLICATIONS.—The Secretary shall determine, within 210 days after the date the Secretary receives an application by a private accrediting organization and using the criteria specified in section 1865(b)(2), whether the process of the private accrediting organization meets the requirements with respect to any specific clause in subpara-

graph (B) with respect to which the application is made. The Secretary may not deny such an application on the basis that it seeks to meet the requirements with respect to only one, or more than one, such specific clause.

“(D) CONSTRUCTION.—Nothing in this paragraph shall be construed as limiting the authority of the Secretary under section 1857, including the authority to terminate contracts with MedicareAdvantage organizations under subsection (c)(2) of such section.

“(5) REPORT TO CONGRESS.—

“(A) IN GENERAL.—The Secretary shall submit to Congress a biennial report regarding how quality assurance programs conducted under this subsection focus on racial and ethnic minorities.

“(B) CONTENTS OF REPORT.—Each such report shall include the following:

“(i) A description of the means by which such programs focus on such racial and ethnic minorities.

“(ii) An evaluation of the impact of such programs on eliminating health disparities and on improving health outcomes,

continuity and coordination of care, management of chronic conditions, and consumer satisfaction.

“(iii) Recommendations on ways to reduce clinical outcome disparities among racial and ethnic minorities.

“(f) GRIEVANCE MECHANISM.—Each MedicareAdvantage organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and enrollees with MedicareAdvantage plans of the organization under this part.

“(g) COVERAGE DETERMINATIONS, RECONSIDERATIONS, AND APPEALS.—

“(1) DETERMINATIONS BY ORGANIZATION.—

“(A) IN GENERAL.—A MedicareAdvantage organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan of the organization under this part is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service. Subject to paragraph (3), such

1 procedures shall provide for such determination
2 to be made on a timely basis.

3 “(B) EXPLANATION OF DETERMINA-
4 TION.—Such a determination that denies cov-
5 erage, in whole or in part, shall be in writing
6 and shall include a statement in understandable
7 language of the reasons for the denial and a de-
8 scription of the reconsideration and appeals
9 processes.

10 “(2) RECONSIDERATIONS.—

11 “(A) IN GENERAL.—The organization shall
12 provide for reconsideration of a determination
13 described in paragraph (1)(B) upon request by
14 the enrollee involved. The reconsideration shall
15 be within a time period specified by the Sec-
16 retary, but shall be made, subject to paragraph
17 (3), not later than 60 days after the date of the
18 receipt of the request for reconsideration.

19 “(B) PHYSICIAN DECISION ON CERTAIN
20 RECONSIDERATIONS.—A reconsideration relat-
21 ing to a determination to deny coverage based
22 on a lack of medical necessity shall be made
23 only by a physician with appropriate expertise
24 in the field of medicine which necessitates treat-

ment who is other than a physician involved in the initial determination.

“(3) EXPEDITED DETERMINATIONS AND RECONSIDERATIONS.—

“(A) RECEIPT OF REQUESTS.—

“(i) ENROLLEE REQUESTS.—An enrollee in a MedicareAdvantage plan may request, either in writing or orally, an expedited determination under paragraph (1) or an expedited reconsideration under paragraph (2) by the MedicareAdvantage organization.

“(ii) PHYSICIAN REQUESTS.—A physician, regardless whether the physician is affiliated with the organization or not, may request, either in writing or orally, such an expedited determination or reconsideration.

“(B) ORGANIZATION PROCEDURES.—

“(i) IN GENERAL.—The MedicareAdvantage organization shall maintain procedures for expediting organization determinations and reconsiderations when, upon request of an enrollee, the organization determines that the application of the normal timeframe for making a de-

1 termination (or a reconsideration involving
 2 a determination) could seriously jeopardize
 3 the life or health of the enrollee or the en-
 4 rollee's ability to regain maximum func-
 5 tion.

6 “(ii) EXPEDITION REQUIRED FOR
 7 PHYSICIAN REQUESTS.—In the case of a
 8 request for an expedited determination or
 9 reconsideration made under subparagraph
 10 (A)(ii), the organization shall expedite the
 11 determination or reconsideration if the re-
 12 quest indicates that the application of the
 13 normal timeframe for making a determina-
 14 tion (or a reconsideration involving a de-
 15 termination) could seriously jeopardize the
 16 life or health of the enrollee or the enroll-
 17 ee's ability to regain maximum function.

18 “(iii) TIMELY RESPONSE.—In cases
 19 described in clauses (i) and (ii), the organi-
 20 zation shall notify the enrollee (and the
 21 physician involved, as appropriate) of the
 22 determination or reconsideration under
 23 time limitations established by the Sec-
 24 retary, but not later than 72 hours of the
 25 time of receipt of the request for the deter-

mination or reconsideration (or receipt of the information necessary to make the determination or reconsideration), or such longer period as the Secretary may permit in specified cases.

“(4) INDEPENDENT REVIEW OF CERTAIN COVERAGE DENIALS.—The Secretary shall contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage, in whole or in part. The provisions of section 1869(c)(5) shall apply to independent outside entities under contract with the Secretary under this paragraph.

“(5) APPEALS.—An enrollee with a MedicareAdvantage plan of a MedicareAdvantage organization under this part who is dissatisfied by reason of the enrollee’s failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay is entitled, if the amount in controversy is \$100 or more, to a hearing before the Secretary to the same extent as is provided in section 205(b), and in any such hearing the Secretary shall make the organization a party. If the amount in controversy is \$1,000 or

1 more, the individual or organization shall, upon noti-
2 fying the other party, be entitled to judicial review
3 of the Secretary's final decision as provided in sec-
4 tion 205(g), and both the individual and the organi-
5 zation shall be entitled to be parties to that judicial
6 review. In applying subsections (b) and (g) of section
7 205 as provided in this paragraph, and in applying
8 section 205(l) thereto, any reference therein to the
9 Commissioner of Social Security or the Social Secu-
10 rity Administration shall be considered a reference
11 to the Secretary or the Department of Health and
12 Human Services, respectively.

13 “(h) CONFIDENTIALITY AND ACCURACY OF EN-
14 ROLLEE RECORDS.—Insofar as a MedicareAdvantage or-
15 ganization maintains medical records or other health in-
16 formation regarding enrollees under this part, the
17 MedicareAdvantage organization shall establish proce-
18 dures—

19 “(1) to safeguard the privacy of any individ-
20 ually identifiable enrollee information;

21 “(2) to maintain such records and information
22 in a manner that is accurate and timely; and

23 “(3) to assure timely access of enrollees to such
24 records and information.

1 “(i) INFORMATION ON ADVANCE DIRECTIVES.—Each
 2 MedicareAdvantage organization shall meet the require-
 3 ment of section 1866(f) (relating to maintaining written
 4 policies and procedures respecting advance directives).

5 “(j) RULES REGARDING PROVIDER PARTICIPA-
 6 TION.—

7 “(1) PROCEDURES.—Insofar as a
 8 MedicareAdvantage organization offers benefits
 9 under a MedicareAdvantage plan through agree-
 10 ments with physicians, the organization shall estab-
 11 lish reasonable procedures relating to the participa-
 12 tion (under an agreement between a physician and
 13 the organization) of physicians under such a plan.
 14 Such procedures shall include—

15 “(A) providing notice of the rules regard-
 16 ing participation;

17 “(B) providing written notice of participa-
 18 tion decisions that are adverse to physicians;
 19 and

20 “(C) providing a process within the organi-
 21 zation for appealing such adverse decisions, in-
 22 cluding the presentation of information and
 23 views of the physician regarding such decision.

24 “(2) CONSULTATION IN MEDICAL POLICIES.—A
 25 MedicareAdvantage organization shall consult with

1 physicians who have entered into participation
2 agreements with the organization regarding the or-
3 ganization's medical policy, quality, and medical
4 management procedures.

5 “(3) PROHIBITING INTERFERENCE WITH PRO-
6 VIDER ADVICE TO ENROLLEES.—

7 “(A) IN GENERAL.—Subject to subpara-
8 graphs (B) and (C), a MedicareAdvantage orga-
9 nization (in relation to an individual enrolled
10 under a MedicareAdvantage plan offered by the
11 organization under this part) shall not prohibit
12 or otherwise restrict a covered health care pro-
13 fessional (as defined in subparagraph (D)) from
14 advising such an individual who is a patient of
15 the professional about the health status of the
16 individual or medical care or treatment for the
17 individual's condition or disease, regardless of
18 whether benefits for such care or treatment are
19 provided under the plan, if the professional is
20 acting within the lawful scope of practice.

21 “(B) CONSCIENCE PROTECTION.—Sub-
22 paragraph (A) shall not be construed as requir-
23 ing a MedicareAdvantage plan to provide, reim-
24 burse for, or provide coverage of a counseling or

referral service if the MedicareAdvantage organization offering the plan—

“(i) objects to the provision of such service on moral or religious grounds; and

“(ii) in the manner and through the written instrumentalities such MedicareAdvantage organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service.

“(C) CONSTRUCTION.—Nothing in subparagraph (B) shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

“(D) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this paragraph, the term ‘health care professional’ means a physician (as defined in section 1861(r)) or other health care professional if coverage for the professional’s services is provided under the

1 MedicareAdvantage plan for the services of the
2 professional. Such term includes a podiatrist,
3 optometrist, chiropractor, psychologist, dentist,
4 licensed pharmacist, physician assistant, phys-
5 ical or occupational therapist and therapy as-
6 sistant, speech-language pathologist, audiol-
7 ogist, registered or licensed practical nurse (in-
8 cluding nurse practitioner, clinical nurse spe-
9 cialist, certified registered nurse anesthetist,
10 and certified nurse-midwife), licensed certified
11 social worker, registered respiratory therapist,
12 and certified respiratory therapy technician.

13 “(4) LIMITATIONS ON PHYSICIAN INCENTIVE
14 PLANS.—

15 “(A) IN GENERAL.—No
16 MedicareAdvantage organization may operate
17 any physician incentive plan (as defined in sub-
18 paragraph (B)) unless the following require-
19 ments are met:

20 “(i) No specific payment is made di-
21 rectly or indirectly under the plan to a
22 physician or physician group as an induce-
23 ment to reduce or limit medically necessary
24 services provided with respect to a specific
25 individual enrolled with the organization.

“(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the organization—

“(I) provides stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or group; and

“(II) conducts periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.

1 “(iii) The organization provides the
2 Secretary with descriptive information re-
3 garding the plan, sufficient to permit the
4 Secretary to determine whether the plan is
5 in compliance with the requirements of this
6 subparagraph.

7 “(B) PHYSICIAN INCENTIVE PLAN DE-
8 FINED.—In this paragraph, the term ‘physician
9 incentive plan’ means any compensation ar-
10 rangement between a MedicareAdvantage orga-
11 nization and a physician or physician group
12 that may directly or indirectly have the effect of
13 reducing or limiting services provided with re-
14 spect to individuals enrolled with the organiza-
15 tion under this part.

16 “(5) LIMITATION ON PROVIDER INDEMNIFICA-
17 TION.—A MedicareAdvantage organization may not
18 provide (directly or indirectly) for a health care pro-
19 fessional, provider of services, or other entity pro-
20 viding health care services (or group of such profes-
21 sionals, providers, or entities) to indemnify the orga-
22 nization against any liability resulting from a civil
23 action brought for any damage caused to an enrollee
24 with a MedicareAdvantage plan of the organization

under this part by the organization's denial of medically necessary care.

“(6) SPECIAL RULES FOR
MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE
PLANS.—For purposes of applying this part (including subsection (k)(1)) and section 1866(a)(1)(O), a hospital (or other provider of services), a physician or other health care professional, or other entity furnishing health care services is treated as having an agreement or contract in effect with a MedicareAdvantage organization (with respect to an individual enrolled in a MedicareAdvantage private fee-for-service plan it offers), if—

“(A) the provider, professional, or other entity furnishes services that are covered under the plan to such an enrollee; and

“(B) before providing such services, the provider, professional, or other entity —

“(i) has been informed of the individual's enrollment under the plan; and

“(ii) either—

“(I) has been informed of the terms and conditions of payment for such services under the plan; or

1 “(II) is given a reasonable oppor-
 2 tunity to obtain information con-
 3 cerning such terms and conditions,
 4 in a manner reasonably designed to effect
 5 informed agreement by a provider.

6 The previous sentence shall only apply in the ab-
 7 sence of an explicit agreement between such a pro-
 8 vider, professional, or other entity and the
 9 MedicareAdvantage organization.

10 “(k) TREATMENT OF SERVICES FURNISHED BY CER-
 11 TAIN PROVIDERS.—

12 “(1) IN GENERAL.—Except as provided in para-
 13 graph (2), a physician or other entity (other than a
 14 provider of services) that does not have a contract
 15 establishing payment amounts for services furnished
 16 to an individual enrolled under this part with a
 17 MedicareAdvantage organization described in section
 18 1851(a)(2)(A) shall accept as payment in full for
 19 covered services under this title that are furnished to
 20 such an individual the amounts that the physician or
 21 other entity could collect if the individual were not
 22 so enrolled. Any penalty or other provision of law
 23 that applies to such a payment with respect to an
 24 individual entitled to benefits under this title (but
 25 not enrolled with a MedicareAdvantage organization

under this part) also applies with respect to an individual so enrolled.

“(2) APPLICATION TO MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS.—

“(A) BALANCE BILLING LIMITS UNDER MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS IN CASE OF CONTRACT PROVIDERS.—

“(i) IN GENERAL.—In the case of an individual enrolled in a MedicareAdvantage private fee-for-service plan under this part, a physician, provider of services, or other entity that has a contract (including through the operation of subsection (j)(6)) establishing a payment rate for services furnished to the enrollee shall accept as payment in full for covered services under this title that are furnished to such an individual an amount not to exceed (including any deductibles, coinsurance, copayments, or balance billing otherwise permitted under the plan) an amount equal to 115 percent of such payment rate.

“(ii) PROCEDURES TO ENFORCE LIMITS.—The MedicareAdvantage organization

1 that offers such a plan shall establish pro-
 2 cedures, similar to the procedures de-
 3 scribed in section 1848(g)(1)(A), in order
 4 to carry out clause (i).

5 “(iii) ASSURING ENFORCEMENT.—If
 6 the MedicareAdvantage organization fails
 7 to establish and enforce procedures re-
 8 quired under clause (ii), the organization is
 9 subject to intermediate sanctions under
 10 section 1857(g).

11 “(B) ENROLLEE LIABILITY FOR NONCON-
 12 TRACT PROVIDERS.—For provisions—

13 “(i) establishing a minimum payment
 14 rate in the case of noncontract providers
 15 under a MedicareAdvantage private fee-
 16 for-service plan, see section 1852(a)(2); or

17 “(ii) limiting enrollee liability in the
 18 case of covered services furnished by such
 19 providers, see paragraph (1) and section
 20 1866(a)(1)(O).

21 “(C) INFORMATION ON BENEFICIARY LI-
 22 ABILITY.—

23 “(i) IN GENERAL.—Each
 24 MedicareAdvantage organization that of-
 25 fers a MedicareAdvantage private fee-for-

1 service plan shall provide that enrollees
2 under the plan who are furnished services
3 for which payment is sought under the
4 plan are provided an appropriate expla-
5 nation of benefits (consistent with that
6 provided under parts A, B, and D, and, if
7 applicable, under medicare supplemental
8 policies) that includes a clear statement of
9 the amount of the enrollee's liability (in-
10 cluding any liability for balance billing con-
11 sistent with this subsection) with respect to
12 payments for such services.

13 “(ii) ADVANCE NOTICE BEFORE RE-
14 CEIPT OF INPATIENT HOSPITAL SERVICES
15 AND CERTAIN OTHER SERVICES.—In addi-
16 tion, such organization shall, in its terms
17 and conditions of payments to hospitals for
18 inpatient hospital services and for other
19 services identified by the Secretary for
20 which the amount of the balance billing
21 under subparagraph (A) could be substan-
22 tial, require the hospital to provide to the
23 enrollee, before furnishing such services
24 and if the hospital imposes balance billing
25 under subparagraph (A)—

1 “(I) notice of the fact that bal-
 2 ance billing is permitted under such
 3 subparagraph for such services; and

4 “(II) a good faith estimate of the
 5 likely amount of such balance billing
 6 (if any), with respect to such services,
 7 based upon the presenting condition
 8 of the enrollee.

9 “(I) RETURN TO HOME SKILLED NURSING FACILI-
 10 TIES FOR COVERED POST-HOSPITAL EXTENDED CARE
 11 SERVICES.—

12 “(1) ENSURING RETURN TO HOME SNF.—

13 “(A) IN GENERAL.—In providing coverage
 14 of post-hospital extended care services, a
 15 MedicareAdvantage plan shall provide for such
 16 coverage through a home skilled nursing facility
 17 if the following conditions are met:

18 “(i) ENROLLEE ELECTION.—The en-
 19 rollee elects to receive such coverage
 20 through such facility.

21 “(ii) SNF AGREEMENT.—The facility
 22 has a contract with the MedicareAdvantage
 23 organization for the provision of such serv-
 24 ices, or the facility agrees to accept sub-
 25 stantially similar payment under the same

terms and conditions that apply to simi-
 particularly situated skilled nursing facilities that
 are under contract with the
 MedicareAdvantage organization for the
 provision of such services and through
 which the enrollee would otherwise receive
 such services.

“(B) MANNER OF PAYMENT TO HOME
 SNF.—The organization shall provide payment
 to the home skilled nursing facility consistent
 with the contract or the agreement described in
 subparagraph (A)(ii), as the case may be.

“(2) NO LESS FAVORABLE COVERAGE.—The
 coverage provided under paragraph (1) (including
 scope of services, cost-sharing, and other criteria of
 coverage) shall be no less favorable to the enrollee
 than the coverage that would be provided to the en-
 rollee with respect to a skilled nursing facility the
 post-hospital extended care services of which are
 otherwise covered under the MedicareAdvantage
 plan.

“(3) RULE OF CONSTRUCTION.—Nothing in
 this subsection shall be construed to do the fol-
 lowing:

1 “(A) To require coverage through a skilled
2 nursing facility that is not otherwise qualified
3 to provide benefits under part A for medicare
4 beneficiaries not enrolled in a
5 MedicareAdvantage plan.

6 “(B) To prevent a skilled nursing facility
7 from refusing to accept, or imposing conditions
8 upon the acceptance of, an enrollee for the re-
9 ceipt of post-hospital extended care services.

10 “(4) DEFINITIONS.—In this subsection:

11 “(A) HOME SKILLED NURSING FACIL-
12 ITY.—The term ‘home skilled nursing facility’
13 means, with respect to an enrollee who is enti-
14 tled to receive post-hospital extended care serv-
15 ices under a MedicareAdvantage plan, any of
16 the following skilled nursing facilities:

17 “(i) SNF RESIDENCE AT TIME OF AD-
18 MISSION.—The skilled nursing facility in
19 which the enrollee resided at the time of
20 admission to the hospital preceding the re-
21 ceipt of such post-hospital extended care
22 services.

23 “(ii) SNF IN CONTINUING CARE RE-
24 TIREMENT COMMUNITY.—A skilled nursing
25 facility that is providing such services

through a continuing care retirement community (as defined in subparagraph (B)) which provided residence to the enrollee at the time of such admission.

“(iii) SNF RESIDENCE OF SPOUSE AT TIME OF DISCHARGE.—The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from such hospital.

“(B) CONTINUING CARE RETIREMENT COMMUNITY.—The term ‘continuing care retirement community’ means, with respect to an enrollee in a MedicareAdvantage plan, an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period.”.

SEC. 203. PAYMENTS TO MEDICAREADVANTAGE ORGANIZATIONS.

Section 1853 (42 U.S.C. 1395w-23) is amended to read as follows:

“PAYMENTS TO MEDICAREADVANTAGE ORGANIZATIONS

“SEC. 1853. (a) PAYMENTS TO ORGANIZATIONS.—

“(1) MONTHLY PAYMENTS.—

1 “(A) IN GENERAL.—Under a contract
 2 ~~fees~~ under section 1857 and subject to subsections
 3 (f), (h), and (j) and section 1859(e)(4), the Sec-
 4 retary shall make, to each MedicareAdvantage
 5 organization, with respect to coverage of an in-
 6 dividual for a month under this part in a
 7 MedicareAdvantage payment area, separate
 8 monthly payments with respect to—

9 “(i) benefits under the original medi-
 10 care fee-for-service program under parts A
 11 and B in accordance with subsection (d);
 12 and

13 “(ii) benefits under the voluntary pre-
 14 scription drug program under part D in
 15 ~~fees~~ accordance with section 1858A and the
 16 ~~the~~ other provisions of this part.

17 “(B) SPECIAL RULE FOR END-STAGE
 18 RENAL DISEASE.—The Secretary shall establish
 19 separate rates of payment to a
 20 MedicareAdvantage organization with respect to
 21 classes of individuals determined to have end-
 22 stage renal disease and enrolled in a
 23 MedicareAdvantage plan of the organization.
 24 Such rates of payment shall be actuarially
 25 equivalent to rates paid to other enrollees in the

1 MedicareAdvantage payment area (or such
2 other area as specified by the Secretary). In ac-
3 cordance with regulations, the Secretary shall
4 provide for the application of the seventh sen-
5 tence of section 1881(b)(7) to payments under
6 this section covering the provision of renal di-
7 alysis treatment in the same manner as such
8 sentence applies to composite rate payments de-
9 scribed in such sentence. In establishing such
10 rates, the Secretary shall provide for appro-
11 priate adjustments to increase each rate to re-
12 flect the demonstration rate (including the risk
13 adjustment methodology associated with such
14 rate) of the social health maintenance organiza-
15 tion end-stage renal disease capitation dem-
16 onstrations (established by section 2355 of the
17 Deficit Reduction Act of 1984, as amended by
18 section 13567(b) of the Omnibus Budget Rec-
19 onciliation Act of 1993), and shall compute
20 such rates by taking into account such factors
21 as renal treatment modality, age, and the un-
22 derlying cause of the end-stage renal disease.

23 “(2) ADJUSTMENT TO REFLECT NUMBER OF
24 ENROLLEES.—

1 “(A) IN GENERAL.—The amount of pay-
2 ment under this subsection may be retroactively
3 adjusted to take into account any difference be-
4 tween the actual number of individuals enrolled
5 with an organization under this part and the
6 number of such individuals estimated to be so
7 enrolled in determining the amount of the ad-
8 vance payment.

9 “(B) SPECIAL RULE FOR CERTAIN EN-
10 ROLLEES.—

11 “(i) IN GENERAL.—Subject to clause
12 (ii), the Secretary may make retroactive
13 adjustments under subparagraph (A) to
14 take into account individuals enrolled dur-
15 ing the period beginning on the date on
16 which the individual enrolls with a
17 MedicareAdvantage organization under a
18 plan operated, sponsored, or contributed to
19 by the individual’s employer or former em-
20 ployer (or the employer or former employer
21 of the individual’s spouse) and ending on
22 the date on which the individual is enrolled
23 in the organization under this part, except
24 that for purposes of making such retro-
25 active adjustments under this subpara-

graph, such period may not exceed 90 days.

“(ii) EXCEPTION.—No adjustment may be made under clause (i) with respect to any individual who does not certify that the organization provided the individual with the disclosure statement described in section 1852(c) at the time the individual enrolled with the organization.

“(C) EQUALIZATION OF FEDERAL CONTRIBUTION.—In applying subparagraph (A), the Secretary shall ensure that the payment to the MedicareAdvantage organization for each individual enrolled with the organization shall equal the MedicareAdvantage benchmark amount for the payment area in which that individual resides (as determined under paragraph (4)), as adjusted—

“(i) by multiplying the benchmark amount for that payment area by the ratio of—

“(I) the payment amount determined under subsection (d)(4); to

1 “(II) the weighted service area
2 benchmark amount determined under
3 subsection (d)(2); and

4 “(ii) using such risk adjustment fac-
5 tor as specified by the Secretary under
6 subsection (b)(1)(B).

7 “(3) COMPREHENSIVE RISK ADJUSTMENT
8 METHODOLOGY.—

9 “(A) APPLICATION OF METHODOLOGY.—
10 The Secretary shall apply the comprehensive
11 risk adjustment methodology described in sub-
12 paragraph (B) to 100 percent of the amount of
13 payments to plans under subsection (d)(4)(B).

14 “(B) COMPREHENSIVE RISK ADJUSTMENT
15 METHODOLOGY DESCRIBED.—The comprehen-
16 sive risk adjustment methodology described in
17 this subparagraph is the risk adjustment meth-
18 odology that would apply with respect to
19 MedicareAdvantage plans offered by
20 MedicareAdvantage organizations in 2005, ex-
21 cept that if such methodology does not apply to
22 groups of beneficiaries who are aged or disabled
23 and groups of beneficiaries who have end-stage
24 renal disease, the Secretary shall revise such
25 methodology to apply to such groups.

1 “(C) UNIFORM APPLICATION TO ALL
2 TYPES OF PLANS.—Subject to section
3 1859(e)(4), the comprehensive risk adjustment
4 methodology established under this paragraph
5 shall be applied uniformly without regard to the
6 type of plan.

7 “(D) DATA COLLECTION.—In order to
8 carry out this paragraph, the Secretary shall re-
9 quire MedicareAdvantage organizations to sub-
10 mit such data and other information as the Sec-
11 retary deems necessary.

12 “(E) IMPROVEMENT OF PAYMENT ACCU-
13 RACY.—Notwithstanding any other provision of
14 this paragraph, the Secretary may revise the
15 comprehensive risk adjustment methodology de-
16 scribed in subparagraph (B) from time to time
17 to improve payment accuracy.

18 “(4) ANNUAL CALCULATION OF BENCHMARK
19 AMOUNTS.—For each year, the Secretary shall cal-
20 culate a benchmark amount for each
21 MedicareAdvantage payment area for each month
22 for such year with respect to coverage of the benefits
23 available under the original medicare fee-for-service
24 program option equal to the greater of the following
25 amounts (adjusted as appropriate for the application

1 of the risk adjustment methodology under paragraph
2 (3)):

3 “(A) MINIMUM AMOUNT.— $\frac{1}{12}$ of the an-
4 nual Medicare+Choice capitation rate deter-
5 mined under subsection (c)(1)(B) for the pay-
6 ment area for the year.

7 “(B) LOCAL FEE-FOR-SERVICE RATE.—
8 The local fee-for-service rate for such area for
9 the year (as calculated under paragraph (5)).

10 “(5) ANNUAL CALCULATION OF LOCAL FEE-
11 FOR-SERVICE RATES.—

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (B), the term ‘local fee-for-service rate’
14 means the amount of payment for a month in
15 a MedicareAdvantage payment area for benefits
16 under this title and associated claims processing
17 costs for an individual who has elected to re-
18 ceive benefits under the original medicare fee-
19 for-service program option and not enrolled in
20 a MedicareAdvantage plan under this part. The
21 Secretary shall annually calculate such amount
22 in a manner similar to the manner in which the
23 Secretary calculated the adjusted average per
24 capita cost under section 1876.

“(B) REMOVAL OF MEDICAL EDUCATION COSTS FROM CALCULATION OF LOCAL FEE-FOR-SERVICE RATE.—

“(i) IN GENERAL.—In calculating the local fee-for-service rate under subparagraph (A) for a year, the amount of payment described in such subparagraph shall be adjusted to exclude from such payment the payment adjustments described in clause (ii).

“(ii) PAYMENT ADJUSTMENTS DESCRIBED.—

“(I) IN GENERAL.—Subject to subclause (II), the payment adjustments described in this subparagraph are payment adjustments which the Secretary estimates are payable during the year—

“(aa) for the indirect costs of medical education under section 1886(d)(5)(B); and

“(bb) for direct graduate medical education costs under section 1886(h).

1 “(II) TREATMENT OF PAYMENTS
2 COVERED UNDER STATE HOSPITAL
3 REIMBURSEMENT SYSTEM.—To the
4 extent that the Secretary estimates
5 that the amount of the local fee-for-
6 service rates reflects payments to hos-
7 pitals reimbursed under section
8 1814(b)(3), the Secretary shall esti-
9 mate a payment adjustment that is
10 comparable to the payment adjust-
11 ment that would have been made
12 under clause (i) if the hospitals had
13 not been reimbursed under such sec-
14 tion.

15 “(b) ANNUAL ANNOUNCEMENT OF PAYMENT FAC-
16 TORS.—

17 “(1) ANNUAL ANNOUNCEMENT.—Beginning in
18 2005, at the same time as the Secretary publishes
19 the risk adjusters under section 1860D-11, the Sec-
20 retary shall annually announce (in a manner in-
21 tended to provide notice to interested parties) the
22 following payment factors:

23 “(A) The benchmark amount for each
24 MedicareAdvantage payment area (as calculated
25 under subsection (a)(4)) for the year.

“(B) The factors to be used for adjusting payments under the comprehensive risk adjustment methodology described in subsection (a)(3)(B) with respect to each MedicareAdvantage payment area for the year.

“(2) ADVANCE NOTICE OF METHODOLOGICAL CHANGES.—At least 45 days before making the announcement under paragraph (1) for a year, the Secretary shall—

“(A) provide for notice to MedicareAdvantage organizations of proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement; and

“(B) provide such organizations with an opportunity to comment on such proposed changes.

“(3) EXPLANATION OF ASSUMPTIONS.—In each announcement made under paragraph (1), the Secretary shall include an explanation of the assumptions and changes in methodology used in the announcement in sufficient detail so that MedicareAdvantage organizations can compute each payment factor described in paragraph (1).

1 “(e) CALCULATION OF ANNUAL MEDICARE+CHOICE
2 CAPITATION RATES.—

3 “(1) IN GENERAL.—For purposes of making
4 payments under this part for years before 2006 and
5 for purposes of calculating the annual
6 Medicare+Choice capitation rates under paragraph
7 (7) beginning with such year, subject to paragraph
8 (6)(C), each annual Medicare+Choice capitation
9 rate, for a Medicare+Choice payment area before
10 2006 or a MedicareAdvantage payment area begin-
11 ning with such year for a contract year consisting of
12 a calendar year, is equal to the largest of the
13 amounts specified in the following subparagraph (A),
14 (B), or (C):

15 “(A) BLENDED CAPITATION RATE.—The
16 sum of—

17 “(i) the area-specific percentage (as
18 specified under paragraph (2) for the year)
19 of the annual area-specific
20 Medicare+Choice capitation rate for the
21 MedicareAdvantage payment area, as de-
22 termined under paragraph (3) for the year;
23 and

24 “(ii) the national percentage (as speci-
25 fied under paragraph (2) for the year) of

the input-price-adjusted annual national Medicare+Choice capitation rate, as determined under paragraph (4) for the year, multiplied by the budget neutrality adjustment factor determined under paragraph (5).

“(B) MINIMUM AMOUNT.—12 multiplied by the following amount:

“(i) For 1998, \$367 (but not to exceed, in the case of an area outside the 50 States and the District of Columbia, 150 percent of the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) for the area).

“(ii) For 1999 and 2000, the minimum amount determined under clause (i) or this clause, respectively, for the preceding year, increased by the national per capita Medicare+Choice growth percentage described in paragraph (6)(A) applicable to 1999 or 2000, respectively.

“(iii)(I) Subject to subclause (II), for 2001, for any area in a Metropolitan Statistical Area with a population of more than 250,000, \$525, and for any other area \$475.

1 “(II) In the case of an area outside
2 the 50 States and the District of Colum-
3 bia, the amount specified in this clause
4 shall not exceed 120 percent of the amount
5 determined under clause (ii) for such area
6 for 2000.

7 “(iv) For 2002 through 2013, the
8 minimum amount specified in this clause
9 (or clause (iii)) for the preceding year in-
10 creased by the national per capita
11 Medicare+Choice growth percentage, de-
12 scribed in paragraph (6)(A) for that suc-
13 ceeding year.

14 “(v) For 2014 and each succeeding
15 year, the minimum amount specified in
16 this clause (or clause (iv)) for the pre-
17 ceding year increased by the percentage in-
18 crease in the Consumer Price Index for all
19 urban consumers (U.S. urban average) for
20 the 12-month period ending with June of
21 the previous year.

22 “(C) MINIMUM PERCENTAGE INCREASE.—

23 “(i) For 1998, 102 percent of the an-
24 nual per capita rate of payment for 1997

1 determined under section 1876(a)(1)(C)

2 for the Medicare+Choice payment area.

3 “(ii) For 1999 and 2000, 102 percent

4 of the annual Medicare+Choice capitation

5 rate under this paragraph for the area for

6 the previous year.

7 “(iii) For 2001, 103 percent of the

8 annual Medicare+Choice capitation rate

9 under this paragraph for the area for

10 2000.

11 “(iv) For 2002, 2003, and 2004, 102

12 percent of the annual Medicare+Choice

13 capitation rate under this paragraph for

14 the area for the previous year.

15 “(v) For 2005, 103 percent of the an-

16 nual Medicare+Choice capitation rate

17 under this paragraph for the area for

18 2003.

19 “(vi) For 2006 and each succeeding

20 year, 102 percent of the annual

21 Medicare+Choice capitation rate under

22 this paragraph for the area for the pre-

23 vious year, except that such rate shall be

24 determined by substituting ‘102’ for ‘103’

25 in clause (v).

1 “(2) AREA-SPECIFIC AND NATIONAL PERCENT-
2 AGES.—For purposes of paragraph (1)(A)—

3 “(A) for 1998, the ‘area-specific percent-
4 age’ is 90 percent and the ‘national percentage’
5 is 10 percent;

6 “(B) for 1999, the ‘area-specific percent-
7 age’ is 82 percent and the ‘national percentage’
8 is 18 percent;

9 “(C) for 2000, the ‘area-specific percent-
10 age’ is 74 percent and the ‘national percentage’
11 is 26 percent;

12 “(D) for 2001, the ‘area-specific percent-
13 age’ is 66 percent and the ‘national percentage’
14 is 34 percent;

15 “(E) for 2002, the ‘area-specific percent-
16 age’ is 58 percent and the ‘national percentage’
17 is 42 percent; and

18 “(F) for a year after 2002, the ‘area-spe-
19 cific percentage’ is 50 percent and the ‘national
20 percentage’ is 50 percent.

21 “(3) ANNUAL AREA-SPECIFIC
22 MEDICARE+CHOICE CAPITATION RATE.—

23 “(A) IN GENERAL.—For purposes of para-
24 graph (1)(A), subject to subparagraph (B), the
25 annual area-specific Medicare+Choice capita-

tion rate for a Medicare+Choice payment
area—

“(i) for 1998 is, subject to subparagraph (D), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) for the area, increased by the national per capita Medicare+Choice growth percentage for 1998 (described in paragraph (6)(A)); or

“(ii) for a subsequent year is the annual area-specific Medicare+Choice capitation rate for the previous year determined under this paragraph for the area, increased by the national per capita Medicare+Choice growth percentage for such subsequent year.

“(B) REMOVAL OF MEDICAL EDUCATION FROM CALCULATION OF ADJUSTED AVERAGE PER CAPITA COST.—

“(i) IN GENERAL.—In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 1998), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be

1 adjusted to exclude from the rate the ap-
2 plicable percent (specified in clause (ii)) of
3 the payment adjustments described in sub-
4 paragraph (C).

5 “(ii) APPLICABLE PERCENT.—For
6 purposes of clause (i), the applicable per-
7 cent for—

8 “(I) 1998 is 20 percent;

9 “(II) 1999 is 40 percent;

10 “(III) 2000 is 60 percent;

11 “(IV) 2001 is 80 percent; and

12 “(V) a succeeding year is 100
13 percent.

14 “(C) PAYMENT ADJUSTMENT.—

15 “(i) IN GENERAL.—Subject to clause
16 (ii), the payment adjustments described in
17 this subparagraph are payment adjust-
18 ments which the Secretary estimates were
19 payable during 1997—

20 “(I) for the indirect costs of med-
21 ical education under section
22 1886(d)(5)(B); and

23 “(II) for direct graduate medical
24 education costs under section
25 1886(h).

“(ii) TREATMENT OF PAYMENTS COVERED UNDER STATE HOSPITAL REIMBURSEMENT SYSTEM.—To the extent that the Secretary estimates that an annual per capita rate of payment for 1997 described in clause (i) reflects payments to hospitals reimbursed under section 1814(b)(3), the Secretary shall estimate a payment adjustment that is comparable to the payment adjustment that would have been made under clause (i) if the hospitals had not been reimbursed under such section.

“(D) TREATMENT OF AREAS WITH HIGHLY VARIABLE PAYMENT RATES.—In the case of a Medicare+Choice payment area for which the annual per capita rate of payment determined under section 1876(a)(1)(C) for 1997 varies by more than 20 percent from such rate for 1996, for purposes of this subsection the Secretary may substitute for such rate for 1997 a rate that is more representative of the costs of the enrollees in the area.

“(4) INPUT-PRICE-ADJUSTED ANNUAL NATIONAL MEDICARE+CHOICE CAPITATION RATE.—

1 “(A) IN GENERAL.—For purposes of para-
2 graph (1)(A), the input-price-adjusted annual
3 national Medicare+Choice capitation rate for a
4 Medicare+Choice payment area for a year is
5 equal to the sum, for all the types of medicare
6 services (as classified by the Secretary), of the
7 product (for each such type of service) of—

8 “(i) the national standardized annual
9 Medicare+Choice capitation rate (deter-
10 mined under subparagraph (B)) for the
11 year;

12 “(ii) the proportion of such rate for
13 the year which is attributable to such type
14 of services; and

15 “(iii) an index that reflects (for that
16 year and that type of services) the relative
17 input price of such services in the area
18 compared to the national average input
19 price of such services.

20 In applying clause (iii), the Secretary may, sub-
21 ject to subparagraph (C), apply those indices
22 under this title that are used in applying (or
23 updating) national payment rates for specific
24 areas and localities.

“(B) NATIONAL STANDARDIZED ANNUAL
 MEDICARE+CHOICE CAPITATION RATE.—In
 subparagraph (A)(i), the ‘national standardized
 annual Medicare+Choice capitation rate’ for a
 year is equal to—

“(i) the sum (for all Medicare+Choice
 payment areas) of the product of—

“(I) the annual area-specific
 Medicare+Choice capitation rate for
 that year for the area under para-
 graph (3); and

“(II) the average number of
 medicare beneficiaries residing in that
 area in the year, multiplied by the av-
 erage of the risk factor weights used
 to adjust payments under subsection
 (a)(1)(A) for such beneficiaries in
 such area; divided by

“(ii) the sum of the products de-
 scribed in clause (i)(II) for all areas for
 that year.

“(5) PAYMENT ADJUSTMENT BUDGET NEU-
 TRALITY FACTOR.—For purposes of paragraph
 (1)(A), for each year, the Secretary shall determine
 a budget neutrality adjustment factor so that the

1 aggregate of the payments under this part (other
 2 than those attributable to subsections (a)(3)(C)(iii)
 3 and (i)) shall equal the aggregate payments that
 4 would have been made under this part if payment
 5 were based entirely on area-specific capitation rates.

6 “(6) NATIONAL PER CAPITA
 7 MEDICARE+CHOICE GROWTH PERCENTAGE DE-
 8 FINED.—

9 “(A) IN GENERAL.—In this part, the ‘na-
 10 tional per capita Medicare+Choice growth per-
 11 centage’ for a year is the percentage determined
 12 by the Secretary, by March 1st before the be-
 13 ginning of the year involved, to reflect the Sec-
 14 retary’s estimate of the projected per capita
 15 rate of growth in expenditures under this title
 16 for an individual entitled to (or enrolled for)
 17 benefits under part A and enrolled under part
 18 B, reduced by the number of percentage points
 19 specified in subparagraph (B) for the year. Sep-
 20 arate determinations may be made for aged en-
 21 rollees, disabled enrollees, and enrollees with
 22 end-stage renal disease.

23 “(B) ADJUSTMENT.—The number of per-
 24 centage points specified in this subparagraph
 25 is—

“(i) for 1998, 0.8 percentage points;

“(ii) for 1999, 0.5 percentage points;

“(iii) for 2000, 0.5 percentage points;

“(iv) for 2001, 0.5 percentage points;

“(v) for 2002, 0.3 percentage points;

and

“(vi) for a year after 2002, 0 percentage points.

“(C) ADJUSTMENT FOR OVER OR UNDER
PROJECTION OF NATIONAL PER CAPITA

MEDICARE+CHOICE GROWTH PERCENTAGE.—

Beginning with rates calculated for 1999, before computing rates for a year as described in paragraph (1), the Secretary shall adjust all area-specific and national Medicare+Choice capitation rates (and beginning in 2000, the minimum amount) for the previous year for the differences between the projections of the national per capita Medicare+Choice growth percentage for that year and previous years and the current estimate of such percentage for such years.

“(7) TRANSITION TO MEDICAREADVANTAGE
COMPETITION.—

1 ~~SECTION 1854(a)(4)~~“(A) IN GENERAL.—For each year (begin-
 2 ning with 2006) payments to
 3 ~~SECTION 1854(b)~~ Medicare Advantage plans shall not be computed
 4 under this subsection, but instead shall be
 5 based on the payment amount determined
 6 under subsection (d).

7 ~~SECTION 1854(c)~~“(B) CONTINUED CALCULATION OF CAPI-
 8 TATION RATES.—For each year (beginning with
 9 2006) the Secretary shall calculate and publish
 10 the annual Medicare+Choice capitation rates
 11 under this subsection and shall use the annual
 12 ~~SECTION 1854(d)~~ Medicare+Choice capitation rate determined
 13 under subsection (c)(1) for purposes of deter-
 14 mining the benchmark amount under subsection
 15 ~~SECTION 1854(a)(4)~~ (a)(4).

16 “(d) SECRETARY’S DETERMINATION OF PAYMENT
 17 AMOUNT.— ~~SECTION 1854(e)~~

18 “(1) REVIEW OF PLAN BIDS.—The Secretary
 19 shall review each plan bid submitted under section
 20 1854(a) for the coverage of benefits under the origi-
 21 nal medicare fee-for-service program option to en-
 22 sure that such bids are consistent with the require-
 23 ments under this part and are based on the assump-
 24 tions described in section 1854(a)(2)(A)(iii). ~~SECTION 1854(f)~~

“(2) DETERMINATION OF WEIGHTED SERVICE AREA BENCHMARK AMOUNTS.—The Secretary shall calculate a weighted service area benchmark amount for the benefits under the original medicare fee-for-service program option for each plan equal to the weighted average of the benchmark amounts for benefits under such original medicare fee-for-service program option for the payment areas included in the service area of the plan using the assumptions described in section 1854(a)(2)(A)(iii).

“(3) COMPARISON TO BENCHMARK.—The Secretary shall determine the difference between each plan bid (as adjusted under paragraph (1)) and the weighted service area benchmark amount (as determined under paragraph (2)) for purposes of determining—

“(A) the payment amount under paragraph (4); and

“(B) the additional benefits required and MedicareAdvantage monthly basic beneficiary premiums.

“(4) DETERMINATION OF PAYMENT AMOUNT FOR ORIGINAL MEDICARE FEE-FOR-SERVICE BENEFITS.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), the Secretary shall determine the
3 payment amount for MedicareAdvantage plans
4 for the benefits under the original medicare fee-
5 for-service program option as follows:

6 “(i) BIDS THAT EQUAL OR EXCEED
7 THE BENCHMARK.—In the case of a plan
8 bid that equals or exceeds the weighted
9 service area benchmark amount, the
10 amount of each monthly payment to a
11 MedicareAdvantage organization with re-
12 spect to each individual enrolled in a plan
13 shall be the weighted service area bench-
14 mark amount.

15 “(ii) BIDS BELOW THE BENCH-
16 MARK.—In the case of a plan bid that is
17 less than the weighted service area bench-
18 mark amount, the amount of each monthly
19 payment to a MedicareAdvantage organiza-
20 tion with respect to each individual en-
21 rolled in a plan shall be the weighted serv-
22 ice area benchmark amount reduced by the
23 amount of any premium reduction elected
24 by the plan under section 1854(d)(1)(A)(i).

“(B) APPLICATION OF COMPREHENSIVE
RISK ADJUSTMENT METHODOLOGY.—The Secretary shall adjust the amounts determined under subparagraph (A) using the comprehensive risk adjustment methodology applicable under subsection (a)(3).

“(6) ADJUSTMENT FOR NATIONAL COVERAGE DETERMINATIONS AND LEGISLATIVE CHANGES IN BENEFITS.—If the Secretary makes a determination with respect to coverage under this title or there is a change in benefits required to be provided under this part that the Secretary projects will result in a significant increase in the costs to MedicareAdvantage organizations of providing benefits under contracts under this part (for periods after any period described in section 1852(a)(5)), the Secretary shall appropriately adjust the benchmark amounts or payment amounts (as determined by the Secretary). Such projection and adjustment shall be based on an analysis by the Secretary of the actuarial costs associated with the new benefits.

“(7) BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION DEFINED.—For purposes of this part, the term ‘benefits under the original medicare fee-for-service pro-

1 gram option' means those items and services (other
 2 than hospice care) for which benefits are available
 3 under parts A and B to individuals entitled to, or
 4 enrolled for, benefits under part A and enrolled
 5 under part B, with cost-sharing for those services as
 6 required under parts A and B or an actuarially
 7 equivalent level of cost-sharing as determined in this
 8 part.

9 “(e) MEDICAREADVANTAGE PAYMENT AREA DE-
 10 FINED.—

11 “(1) IN GENERAL.—In this part, except as pro-
 12 vided in paragraph (3), the term
 13 ‘MedicareAdvantage payment area’ means a county,
 14 or equivalent area specified by the Secretary.

15 “(2) RULE FOR ESRD BENEFICIARIES.—In the
 16 case of individuals who are determined to have end
 17 stage renal disease, the MedicareAdvantage payment
 18 area shall be a State or such other payment area as
 19 the Secretary specifies.

20 “(3) GEOGRAPHIC ADJUSTMENT.—

21 “(A) IN GENERAL.—Upon written request
 22 of the chief executive officer of a State for a
 23 contract year (beginning after 2005) made by
 24 not later than February 1 of the previous year,
 25 the Secretary shall make a geographic adjust-

ment to a MedicareAdvantage payment area in the State otherwise determined under paragraph (1)—

“(i) to a single statewide MedicareAdvantage payment area;

“(ii) to the metropolitan based system described in subparagraph (C); or

“(iii) to consolidating into a single MedicareAdvantage payment area non-contiguous counties (or equivalent areas described in paragraph (1)) within a State.

Such adjustment shall be effective for payments for months beginning with January of the year following the year in which the request is received.

“(B) BUDGET NEUTRALITY ADJUSTMENT.—In the case of a State requesting an adjustment under this paragraph, the Secretary shall initially (and annually thereafter) adjust the payment rates otherwise established under this section for MedicareAdvantage payment areas in the State in a manner so that the aggregate of the payments under this section in the State shall not exceed the aggregate payments that would have been made under this

section for MedicareAdvantage payment areas in the State in the absence of the adjustment under this paragraph.

“(C) METROPOLITAN BASED SYSTEM.—

The metropolitan based system described in this subparagraph is one in which—

“(i) all the portions of each metropolitan statistical area in the State or in the case of a consolidated metropolitan statistical area, all of the portions of each primary metropolitan statistical area within the consolidated area within the State, are treated as a single MedicareAdvantage payment area; and

“(ii) all areas in the State that do not fall within a metropolitan statistical area are treated as a single MedicareAdvantage payment area.

“(D) AREAS.—In subparagraph (C), the terms ‘metropolitan statistical area’, ‘consolidated metropolitan statistical area’, and ‘primary metropolitan statistical area’ mean any area designated as such by the Secretary of Commerce.

1 “(f) SPECIAL RULES FOR INDIVIDUALS ELECTING
2 MSA PLANS.—

3 “(1) IN GENERAL.—If the amount of the
4 MedicareAdvantage monthly MSA premium (as de-
5 fined in section 1854(b)(2)(D)) for an MSA plan for
6 a year is less than $\frac{1}{12}$ of the annual
7 Medicare+Choice capitation rate applied under this
8 section for the area and year involved, the Secretary
9 shall deposit an amount equal to 100 percent of
10 such difference in a MedicareAdvantage MSA estab-
11 lished (and, if applicable, designated) by the indi-
12 vidual under paragraph (2).

13 “(2) ESTABLISHMENT AND DESIGNATION OF
14 MEDICAREADVANTAGE MEDICAL SAVINGS ACCOUNT
15 AS REQUIREMENT FOR PAYMENT OF CONTRIBU-
16 TION.—In the case of an individual who has elected
17 coverage under an MSA plan, no payment shall be
18 made under paragraph (1) on behalf of an individual
19 for a month unless the individual—

20 “(A) has established before the beginning
21 of the month (or by such other deadline as the
22 Secretary may specify) a MedicareAdvantage
23 MSA (as defined in section 138(b)(2) of the In-
24 ternal Revenue Code of 1986); and

1 “(B) if the individual has established more
 2 than 1 such MedicareAdvantage MSA, has des-
 3 ignated 1 of such accounts as the individual’s
 4 MedicareAdvantage MSA for purposes of this
 5 part.

6 Under rules under this section, such an individual
 7 may change the designation of such account under
 8 subparagraph (B) for purposes of this part.

9 “(3) LUMP-SUM DEPOSIT OF MEDICAL SAVINGS
 10 ACCOUNT CONTRIBUTION.—In the case of an indi-
 11 vidual electing an MSA plan effective beginning with
 12 a month in a year, the amount of the contribution
 13 to the MedicareAdvantage MSA on behalf of the in-
 14 dividual for that month and all successive months in
 15 the year shall be deposited during that first month.
 16 In the case of a termination of such an election as
 17 of a month before the end of a year, the Secretary
 18 shall provide for a procedure for the recovery of de-
 19 posits attributable to the remaining months in the
 20 year.

21 “(g) PAYMENTS FROM TRUST FUNDS.—Except as
 22 provided in section 1858A(c) (relating to payments for
 23 qualified prescription drug coverage), the payment to a
 24 MedicareAdvantage organization under this section for in-
 25 dividuals enrolled under this part with the organization

1 and payments to a MedicareAdvantage MSA under sub-
 2 section (e)(1) shall be made from the Federal Hospital In-
 3 surance Trust Fund and the Federal Supplementary Med-
 4 ical Insurance Trust Fund in such proportion as the Sec-
 5 retary determines reflects the relative weight that benefits
 6 under part A and under part B represents of the actuarial
 7 value of the total benefits under this title. Monthly pay-
 8 ments otherwise payable under this section for October
 9 2000 shall be paid on the first business day of such month.
 10 Monthly payments otherwise payable under this section
 11 for October 2001 shall be paid on the last business day
 12 of September 2001. Monthly payments otherwise payable
 13 under this section for October 2006 shall be paid on the
 14 first business day of October 2006.

15 “(h) SPECIAL RULE FOR CERTAIN INPATIENT HOS-
 16 PITAL STAYS.—In the case of an individual who is receiv-
 17 ing inpatient hospital services from a subsection (d) hos-
 18 pital (as defined in section 1886(d)(1)(B)) as of the effec-
 19 tive date of the individual’s—

20 “(1) election under this part of a
 21 MedicareAdvantage plan offered by a
 22 MedicareAdvantage organization—

23 “(A) payment for such services until the
 24 — date of the individual’s discharge shall be made
 25 under this title through the MedicareAdvantage

1 plan or the original medicare fee-for-service
 2 program option (as the case may be) elected be-
 3 fore the election with such organization,

4 “(B) the elected organization shall not be
 5 financially responsible for payment for such
 6 services until the date after the date of the indi-
 7 vidual’s discharge; and

8 “(C) the organization shall nonetheless be
 9 paid the full amount otherwise payable to the
 10 organization under this part; or

11 “(2) termination of election with respect to a
 12 MedicareAdvantage organization under this part—

13 “(A) the organization shall be financially
 14 responsible for payment for such services after
 15 such date and until the date of the individual’s
 16 discharge;

17 “(B) payment for such services during the
 18 stay shall not be made under section 1886(d) or
 19 by any succeeding MedicareAdvantage organiza-
 20 tion; and

21 “(C) the terminated organization shall not
 22 receive any payment with respect to the indi-
 23 vidual under this part during the period the in-
 24 dividual is not enrolled.

25 “(i) SPECIAL RULE FOR HOSPICE CARE.—

1 “(1) INFORMATION.—A contract under this
2 part shall require the MedicareAdvantage organiza-
3 tion to inform each individual enrolled under this
4 part with a MedicareAdvantage plan offered by the
5 organization about the availability of hospice care
6 if—

7 “(A) a hospice program participating
8 under this title is located within the organiza-
9 tion’s service area; or

10 “(B) it is common practice to refer pa-
11 tients to hospice programs outside such service
12 area.

13 “(2) PAYMENT.—If an individual who is en-
14 rolled with a MedicareAdvantage organization under
15 this part makes an election under section 1812(d)(1)
16 to receive hospice care from a particular hospice pro-
17 gram—

18 “(A) payment for the hospice care fur-
19 nished to the individual shall be made to the
20 hospice program elected by the individual by
21 the Secretary;

22 “(B) payment for other services for which
23 the individual is eligible notwithstanding the in-
24 dividual’s election of hospice care under section
25 1812(d)(1), including services not related to the

1 individual's terminal illness, shall be made by
 2 the Secretary to the MedicareAdvantage organi-
 3 zation or the provider or supplier of the service
 4 instead of payments calculated under subsection
 5 (a); and

6 “(C) the Secretary shall continue to make
 7 monthly payments to the MedicareAdvantage
 8 organization in an amount equal to the value of
 9 the additional benefits required under section
 10 1854(f)(1)(A).”.

11 **SEC. 204. SUBMISSION OF BIDS; PREMIUMS.**

12 Section 1854 (42 U.S.C. 1395w-24) is amended to
 13 read as follows:

14 “SUBMISSION OF BIDS; PREMIUMS

15 “SEC. 1854. (a) SUBMISSION OF BIDS BY
 16 MEDICAREADVANTAGE ORGANIZATIONS.—

17 “(1) IN GENERAL.—Not later than the second
 18 Monday in September and except as provided in
 19 paragraph (3), each MedicareAdvantage organiza-
 20 tion shall submit to the Secretary, in such form and
 21 manner as the Secretary may specify, for each
 22 MedicareAdvantage plan that the organization in-
 23 tends to offer in a service area in the following
 24 year—

25 “(A) notice of such intent and information
 26 on the service area of the plan;

“(B) the plan type for each plan;

“(C) if the Medicare Advantage plan is a coordinated care plan (as described in section 1851(a)(2)(A)) or a private fee-for-service plan (as described in section 1851(a)(2)(C)), the information described in paragraph (2) with respect to each payment area;

“(D) the enrollment capacity (if any) in relation to the plan and each payment area;

“(E) the expected mix, by health status, of enrolled individuals; and

“(F) such other information as the Secretary may specify.

“(2) INFORMATION REQUIRED FOR COORDINATED CARE PLANS AND PRIVATE FEE-FOR-SERVICE PLANS.—For a Medicare Advantage plan that is a coordinated care plan (as described in section 1851(a)(2)(A)) or a private fee-for-service plan (as described in section 1851(a)(2)(C)), the information described in this paragraph is as follows:

“(A) INFORMATION REQUIRED WITH RESPECT TO BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—Information relating to the coverage of

benefits under the original medicare fee-for-service program option as follows:

“(i) The plan bid, which shall consist of a dollar amount that represents the total amount that the plan is willing to accept (not taking into account the application of the comprehensive risk adjustment methodology under section 1853(a)(3)) for providing coverage of the benefits under the original medicare fee-for-service program option to an individual enrolled in the plan that resides in the service area of the plan for a month.

“(ii) For the enhanced medical benefits package offered—

“(I) the adjusted community rate (as defined in subsection (g)(3)) of the package;

“(II) the portion of the actuarial value of such benefits package (if any) that will be applied toward satisfying the requirement for additional benefits under subsection (g);

“(III) the Medicare Advantage monthly beneficiary premium for en-

enhanced medical benefits (as defined in subsection (b)(2)(C));

“(IV) a description of any cost-sharing;

“(V) a description of whether the amount of the unified deductible has been lowered or the maximum limitations on out-of-pocket expenses have been decreased (relative to the levels used in calculating the plan bid);

“(VI) such other information as the Secretary considers necessary.

“(iii) The assumptions that the MedicareAdvantage organization used in preparing the plan bid with respect to numbers, in each payment area, of enrolled individuals and the mix, by health status, of such individuals.

“(B) INFORMATION REQUIRED WITH RESPECT TO PART D.—The information required to be submitted by an eligible entity under section 1860D–12, including the monthly premiums for standard coverage and any other qualified prescription drug coverage available to individuals enrolled under part D.

1 ~~inserted text~~“(C) DETERMINING PLAN COSTS IN-
 2 CLUDED IN PLAN BID.—For purposes of sub-
 3 ~~inserted text~~mitting its plan bid under subparagraph (A)(i)
 4 a MedicareAdvantage plan offered by a
 5 ~~inserted text~~MedicareAdvantage organization satisfies sub-
 6 ~~inserted text~~paragraphs (A) and (C) of section 1852(a)(1) if
 7 the actuarial value of the deductibles, coinsur-
 8 ance, and copayments applicable on average to
 9 individuals enrolled in such plan under this part
 10 with respect to benefits under the original medi-
 11 ~~inserted text~~care fee-for-service program option on which
 12 ~~inserted text~~that bid is based (ignoring any reduction in
 13 ~~inserted text~~cost-sharing offered by such plan as enhanced
 14 medical benefits under paragraph (2)(A)(ii) or
 15 ~~inserted text~~required under clause (ii) or (iii) of subsection
 16 ~~inserted text~~(g)(1)(C)) equals the amount specified in sub-
 17 section (f)(1)(B). ~~inserted text~~

18 “(3) REQUIREMENTS FOR MSA PLANS.—For an
 19 MSA plan described in section 1851(a)(2)(B), the
 20 information described in this paragraph is the infor-
 21 mation that such a plan would have been required
 22 to submit under this part if the Prescription Drug
 23 and Medicare Improvements Act of 2003 had not
 24 been enacted. ~~inserted text~~

25 “(4) REVIEW.— ~~inserted text~~ for a

“(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall review the adjusted community rates (as defined in section 1854(g)(3)), the amounts of the MedicareAdvantage monthly basic premium and the MedicareAdvantage monthly beneficiary premium for enhanced medical benefits filed under this subsection and shall approve or disapprove such rates and amounts so submitted. The Secretary shall review the actuarial assumptions and data used by the MedicareAdvantage organization with respect to such rates and amounts so submitted to determine the appropriateness of such assumptions and data. *ADDITIONAL (A)*

“(B) EXCEPTION.—The Secretary shall not review, approve, or disapprove the amounts submitted under paragraph (3), or, with respect to a private fee-for-service plan (as described in section 1851(a)(2)(C)) under subparagraph (A)(i), (A)(ii)(III), or (B) of paragraph (2). *1*

“(C) CLARIFICATION OF AUTHORITY REGARDING DISAPPROVAL OF UNREASONABLE —BENEFICIARY COST-SHARING.—Under the authority under subparagraph (A), the Secretary

may disapprove the bid if the Secretary determines that the deductibles, coinsurance, or co-payments applicable under the plan discourage access to covered services or are likely to result in favorable selection of MedicareAdvantage eligible individuals.

“(5) APPLICATION OF FEHBP STANDARD; PROHIBITION ON PRICE GOUGING.—Each bid amount submitted under paragraph (1) for a MedicareAdvantage plan must reasonably and equitably reflect the cost of benefits provided under that plan.

“(b) MONTHLY PREMIUMS CHARGED.—

“(1) IN GENERAL.—

“(A) COORDINATED CARE AND PRIVATE FEE-FOR-SERVICE PLANS.—The monthly amount of the premium charged to an individual enrolled in a MedicareAdvantage plan (other than an MSA plan) offered by a MedicareAdvantage organization shall be equal to the sum of the following:

“(i) The MedicareAdvantage monthly basic beneficiary premium (if any).

“(ii) The MedicareAdvantage monthly beneficiary premium for enhanced medical benefits (if any). ~~PREMIUM~~

“(iii) The MedicareAdvantage monthly obligation for qualified prescription drug coverage (if any). ~~OBIGATION~~

“(B) MSA PLANS.—The rules under this section that would have applied with respect to an MSA plan if the Prescription Drug and Medicare Improvements Act of 2003 had not been enacted shall continue to apply to MSA plans after the date of enactment of such Act.

“(2) PREMIUM TERMINOLOGY.—For purposes of this part:

“(A) MEDICAREADVANTAGE MONTHLY BASIC BENEFICIARY PREMIUM.—The term ‘MedicareAdvantage monthly basic beneficiary premium’ means, with respect to a MedicareAdvantage plan, the amount required to be charged under subsection (d)(2) for the plan. ~~PREMIUM~~

“(B) MEDICAREADVANTAGE MONTHLY BENEFICIARY OBLIGATION FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term ‘MedicareAdvantage monthly beneficiary obliga-

1 tion for qualified prescription drug coverage’
 2 means, with respect to a MedicareAdvantage
 3 plan, the amount determined under section
 4 1858A(d).

5 “(C) MEDICAREADVANTAGE MONTHLY
 6 BENEFICIARY PREMIUM FOR ENHANCED MED-
 7 ICAL BENEFITS.—The term
 8 ‘MedicareAdvantage monthly beneficiary pre-
 9 mium for enhanced medical benefits’ means,
 10 with respect to a MedicareAdvantage plan, the
 11 amount required to be charged under sub-
 12 section (f)(2) for the plan, or, in the case of an
 13 MSA plan, the amount filed under subsection
 14 (a)(3).

15 “(D) MEDICAREADVANTAGE MONTHLY
 16 MSA PREMIUM.—The term ‘MedicareAdvantage
 17 monthly MSA premium’ means, with respect to
 18 a MedicareAdvantage plan, the amount of such
 19 premium filed under subsection (a)(3) for the
 20 plan.

21 “(c) UNIFORM PREMIUM.—The MedicareAdvantage
 22 monthly basic beneficiary premium, the
 23 MedicareAdvantage monthly beneficiary obligation for
 24 qualified prescription drug coverage, the
 25 MedicareAdvantage monthly beneficiary premium for en-

1 hanced medical benefits, and the MedicareAdvantage
 2 monthly MSA premium charged under subsection (b) of
 3 a MedicareAdvantage organization under this part may
 4 not vary among individuals enrolled in the plan. Subject
 5 to the provisions of section 1858(h), such requirement
 6 shall not apply to enrollees of a MedicareAdvantage plan
 7 who are enrolled in the plan pursuant to a contractual
 8 agreement between the plan and an employer or other
 9 group health plan that provides employment-based retiree
 10 health coverage (as defined in section 1860D-
 11 20(d)(4)(B)) if the premium amount is the same for all
 12 such enrollees under such agreement.

13 “(d) DETERMINATION OF PREMIUM REDUCTIONS,
 14 REDUCED COST-SHARING, ADDITIONAL BENEFITS, AND
 15 BENEFICIARY PREMIUMS.—

16 “(1) BIDS BELOW THE BENCHMARK.—If the
 17 Secretary determines under section 1853(d)(3) that
 18 the weighted service area benchmark amount ex-
 19 ceeds the plan bid, the Secretary shall require the
 20 plan to provide additional benefits in accordance
 21 with subsection (g).

22 “(2) BIDS ABOVE THE BENCHMARK.—If the
 23 Secretary determines under section 1853(d)(3) that
 24 the plan bid exceeds the weighted service area
 25 benchmark amount (determined under section

1 1853(d)(2)), the amount of such excess shall be the
 2 MedicareAdvantage monthly basic beneficiary pre-
 3 mium (as defined in section 1854(b)(2)(A)).

4 “(e) TERMS AND CONDITIONS OF IMPOSING PRE-
 5 MIUMS.—Each MedicareAdvantage organization shall per-
 6 mit the payment of any MedicareAdvantage monthly basic
 7 premium, the MedicareAdvantage monthly beneficiary ob-
 8 ligation for qualified prescription drug coverage, and the
 9 MedicareAdvantage monthly beneficiary premium for en-
 10 hanced medical benefits on a monthly basis, may termi-
 11 nate election of individuals for a MedicareAdvantage plan
 12 for failure to make premium payments only in accordance
 13 with section 1851(g)(3)(B)(i), and may not provide for
 14 cash or other monetary rebates as an inducement for en-
 15 rollment or otherwise (other than as an additional benefit
 16 described in subsection (g)(1)(C)(i)).

17 “(f) LIMITATION ON ENROLLEE LIABILITY.—

18 “(1) FOR BENEFITS UNDER THE ORIGINAL
 19 MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—

20 The sum of—

21 “(A) the MedicareAdvantage monthly basic
 22 beneficiary premium (multiplied by 12) and the
 23 actuarial value of the deductibles, coinsurance,
 24 and copayments (determined on the same basis
 25 as used in determining the plan’s bid under

1 paragraph (2)(C)) applicable on average to indi-
2 viduals enrolled under this part with a
3 MedicareAdvantage plan described in subpara-
4 graph (A) of section 1851(a)(2) of an organiza-
5 tion with respect to required benefits described
6 in section 1852(a)(1)(A); must equal

7 “(B) the actuarial value of the deductibles,
8 coinsurance, and copayments that would be ap-
9 plicable on average to individuals who have
10 elected to receive benefits under the original
11 medicare fee-for-service program option if such
12 individuals were not members of a
13 MedicareAdvantage organization for the year
14 (adjusted as determined appropriate by the Sec-
15 retary to account for geographic differences and
16 for plan cost and utilization differences).

17 “(2) FOR ENHANCED MEDICAL BENEFITS.—If
18 the MedicareAdvantage organization provides to its
19 members enrolled under this part in a
20 MedicareAdvantage plan described in subparagraph
21 (A) of section 1851(a)(2) with respect to enhanced
22 medical benefits relating to benefits under the origi-
23 nal medicare fee-for-service program option, the sum
24 of the MedicareAdvantage monthly beneficiary pre-
25 mium for enhanced medical benefits (multiplied by

12) charged and the actuarial value of its deductibles, coinsurance, and copayments charged with respect to such benefits for a year must equal the adjusted community rate (as defined in subsection (g)(3)) for such benefits for the year minus the actuarial value of any additional benefits pursuant to clause (ii), (iii), or (iv) of subsection (g)(2)(C) that the plan specified under subsection (a)(2)(i)(II).

“(3) DETERMINATION ON OTHER BASIS.—If the Secretary determines that adequate data are not available to determine the actuarial value under paragraph (1)(A) or (2), the Secretary may determine such amount with respect to all individuals in the same geographic area, the State, or in the United States, eligible to enroll in the MedicareAdvantage plan involved under this part or on the basis of other appropriate data.

“(4) SPECIAL RULE FOR PRIVATE FEE-FOR-SERVICE PLANS.—With respect to a MedicareAdvantage private fee-for-service plan (other than a plan that is an MSA plan), in no event may—

“(A) the actuarial value of the deductibles, coinsurance, and copayments applicable on average to individuals enrolled under this part

with such a plan of an organization with respect to required benefits described in subparagraphs (A), (C), and (D) of section 1852(a)(1);

“(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to individuals entitled to (or enrolled for) benefits under part A and enrolled under part B if they were not members of a MedicareAdvantage organization for the year.

“(g) REQUIREMENT FOR ADDITIONAL BENEFITS.—

“(1) REQUIREMENT.—

“(A) ~~IN~~ IN GENERAL.—Each MedicareAdvantage organization (in relation to a MedicareAdvantage plan, other than an MSA plan, it offers) shall provide that if there is an excess amount (as defined in subparagraph (B)) for the plan for a contract year, subject to the succeeding provisions of this subsection, the organization shall provide to individuals such additional benefits described in subparagraph (C) as the organization may specify in a value which the Secretary determines is at least equal to the adjusted excess amount (as defined in subparagraph (D)).

1 “(B) EXCESS AMOUNT.—For purposes of
2 this paragraph, the term ‘excess amount’
3 means, for an organization for a plan, is 100
4 percent of the amount (if any) by which the
5 weighted service area benchmark amount (de-
6 termined under section 1853(d)(2)) exceeds the
7 plan bid (as adjusted under section
8 1853(d)(1)).

9 “(C) ADDITIONAL BENEFITS DE-
10 SCRIBED.—The additional benefits described in
11 this subparagraph are as follows:

12 “(i) Subject to subparagraph (F), a
13 monthly part B premium reduction for in-
14 dividuals enrolled in the plan.

15 “(ii) Lowering the amount of the uni-
16 fied deductible and decreasing the max-
17 imum limitations on out-of-pocket expenses
18 for individuals enrolled in the plan.

19 “(iii) A reduction in the actuarial
20 value of plan cost-sharing for plan enroll-
21 ees.

22 “(iv) Subject to subparagraph (E),
23 such additional benefits as the organization
24 may specify.

“(v) Contributing to the stabilization
fund under paragraph (2).

“(vi) Any combination of the reduc-
tions and benefits described in clauses (i)
through (v).

“(D) ADJUSTED EXCESS AMOUNT.—For
purposes of this paragraph, the term ‘adjusted
excess amount’ means, for an organization for
a plan, is the excess amount reduced to reflect
any amount withheld and reserved for the orga-
nization for the year under paragraph (2).

“(E) RULE FOR APPROVAL OF MEDICAL
AND PRESCRIPTION DRUG BENEFITS.—An orga-
nization may not specify any additional benefit
that provides for the coverage of any prescrip-
tion drug (other than that relating to prescrip-
tion drugs covered under the original medicare
fee-for-service program option).

“(F) PREMIUM REDUCTIONS.—

“(i) IN GENERAL.—Subject to clause
(ii), as part of providing any additional
benefits required under subparagraph (A),
a MedicareAdvantage organization may
elect a reduction in its payments under
section 1853(a)(1)(A)(i) with respect to a

1 MedicareAdvantage plan and the Secretary
 2 shall apply such reduction to reduce the
 3 premium under section 1839 of each en-
 4 rollee in such plan as provided in section
 5 1840(i).

6 “(ii) AMOUNT OF REDUCTION.—The
 7 amount of the reduction under clause (i)
 8 with respect to any enrollee in a
 9 MedicareAdvantage plan—

10 “(I) may not exceed 125 percent
 11 of the premium described under sec-
 12 tion 1839(a)(3); and

13 “(II) shall apply uniformly to
 14 each enrollee of the
 15 MedicareAdvantage plan to which
 16 such reduction applies.

17 “(G) UNIFORM APPLICATION.—This para-
 18 graph shall be applied uniformly for all enroll-
 19 ees for a plan.

20 “(H) CONSTRUCTION.—Nothing in this
 21 subsection shall be construed as preventing a
 22 MedicareAdvantage organization from providing
 23 enhanced medical benefits (described in section
 24 1852(a)(3)) that are in addition to the health
 25 care benefits otherwise required to be provided

under this paragraph and from imposing a premium for such enhanced medical benefits.

“(2) ~~THE~~ STABILIZATION ~~AND~~ FUND.—A

MedicareAdvantage organization may provide that a part of the value of an excess amount described in paragraph (1) be withheld and reserved in the Federal Hospital Insurance Trust Fund and in the Federal Supplementary Medical Insurance Trust Fund (in such proportions as the Secretary determines to be appropriate) by the Secretary for subsequent annual contract periods, to the extent required to prevent undue fluctuations in the additional benefits offered in those subsequent periods by the organization in accordance with such paragraph. Any of such value of the amount reserved which is not provided as additional benefits described in paragraph (1)(A) to individuals electing the MedicareAdvantage plan of the organization in accordance with such paragraph prior to the end of such periods, shall revert for the use of such Trust Funds.

“(3) ADJUSTED COMMUNITY RATE.—For purposes of this subsection, subject to paragraph (4), the term ‘adjusted community rate’ for a service or services means, at the election of a MedicareAdvantage organization, either—

1 “(A) the rate of payment for that service
2 or services which the Secretary annually deter-
3 mines would apply to an individual electing a
4 MedicareAdvantage plan under this part if the
5 rate of payment were determined under a ‘com-
6 munity rating system’ (as defined in section
7 1302(8) of the Public Health Service Act, other
8 than subparagraph (C)); or *to be determined*

9 “(B) such portion of the weighted aggre-
10 gate premium, which the Secretary annually es-
11 timates would apply to such an individual, as
12 the Secretary annually estimates is attributable
13 to that service or services,

14 but adjusted for differences between the utilization
15 characteristics of the individuals electing coverage
16 under this part and the utilization characteristics of
17 the other enrollees with the plan (or, if the Secretary
18 finds that adequate data are not available to adjust
19 for those differences, the differences between the uti-
20 lization characteristics of individuals selecting other
21 MedicareAdvantage coverage, or MedicareAdvantage
22 eligible individuals in the area, in the State, or in
23 the United States, eligible to elect
24 MedicareAdvantage coverage under this part and the
25 utilization characteristics of the rest of the popu-

lation in the area, in the State, or in the United States, respectively).

“(4) DETERMINATION BASED ON INSUFFICIENT DATA.—For purposes of this subsection, if the Secretary finds that there is insufficient enrollment experience to determine the average amount of payments to be made under this part at the beginning of a contract period or to determine (in the case of a newly operated provider-sponsored organization or other new organization) the adjusted community rate for the organization, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this part and may determine such a rate using data in the general commercial marketplace.

“(h) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES.—No State may impose a premium tax or similar tax with respect to payments to MedicareAdvantage organizations under section 1853.

“(i) PERMITTING USE OF SEGMENTS OF SERVICE AREAS.—The Secretary shall permit a MedicareAdvantage organization to elect to apply the provisions of this section uniformly to separate segments of a service area (rather than uniformly to an entire service area) as long as such

1 segments are composed of 1 or more Medicare Advantage
2 payment areas.”.

3 (b) STUDY AND REPORT ON CLARIFICATION OF AU-
4 THORITY REGARDING DISAPPROVAL OF UNREASONABLE
5 BENEFICIARY COST-SHARING.—

6 (1) STUDY.—The Secretary, in consultation
7 with beneficiaries, consumer groups, employers, and
8 Medicare+Choice organizations, shall conduct a
9 study to determine the extent to which the cost-shar-
10 ing structures under Medicare+Choice plans under
11 part C of title XVIII of the Social Security Act dis-
12 courage access to covered services or discriminate
13 based on the health status of Medicare+Choice eligi-
14 ble individuals (as defined in section 1851(a)(3) of
15 the Social Security Act (42 U.S.C. 1395w-
16 21(a)(3))).

17 (2) REPORT.—Not later than December 31,
18 2004, the Secretary shall submit a report to Con-
19 gress on the study conducted under paragraph (1)
20 together with recommendations for such legislation
21 and administrative actions as the Secretary con-
22 siders appropriate.

1 **SEC. 205. SPECIAL RULES FOR PRESCRIPTION DRUG BENE-**
2 **FITS.**

3 Part C of title XVIII (42 U.S.C. 1395w-21 et seq.)
4 is amended by inserting after section 1857 the following
5 new section:

6 “SPECIAL RULES FOR PRESCRIPTION DRUG BENEFITS

7 “SEC. 1858A. (a) AVAILABILITY.—

8 “(1) PLANS REQUIRED TO PROVIDE QUALIFIED
9 PRESCRIPTION DRUG COVERAGE TO ENROLLEES.—

10 “(A) IN GENERAL.—Except as provided in
11 subparagraph (B), on and after January 1,
12 2006, a MedicareAdvantage organization offer-
13 ing a MedicareAdvantage plan (except for an
14 MSA plan) shall make available qualified pre-
15 scription drug coverage that meets the require-
16 ments for such coverage under this part and
17 part D to each enrollee of the plan.

18 “(B) PRIVATE FEE-FOR-SERVICE PLANS
19 MAY, BUT ARE NOT REQUIRED TO, PROVIDE
20 QUALIFIED PRESCRIPTION DRUG COVERAGE.—

21 Pursuant to section 1852(a)(2)(D), a private
22 fee-for-service plan may elect not to provide
23 qualified prescription drug coverage under part
24 D to individuals residing in the area served by
25 the plan.

1 “(2) REFERENCE TO PROVISION PERMITTING
 2 ADDITIONAL PRESCRIPTION DRUG COVERAGE.—For
 3 the provisions of part D, made applicable to this
 4 part pursuant to paragraph (1), that permit a plan
 5 to make available qualified prescription drug cov-
 6 erage that includes coverage of covered drugs that
 7 exceeds the coverage required under paragraph (1)
 8 of section 1860D-6 in an area, but only if the
 9 MedicareAdvantage organization offering the plan
 10 also offers a MedicareAdvantage plan in the area
 11 that only provides the coverage that is required
 12 under such paragraph (1), see paragraph (2) of such
 13 section.

14 “(3) RULE FOR APPROVAL OF MEDICAL AND
 15 PRESCRIPTION DRUG BENEFITS.—Pursuant to sec-
 16 tions 1854(g)(1)(F) and 1852(a)(3)(D), a
 17 MedicareAdvantage organization offering a
 18 MedicareAdvantage plan that provides qualified pre-
 19 scription drug coverage may not make available cov-
 20 erage of any prescription drugs (other than that re-
 21 lating to prescription drugs covered under the origi-
 22 nal medicare fee-for-service program option) to an
 23 enrollee as an additional benefit or as an enhanced
 24 medical benefit.

1 “(b) COMPLIANCE WITH ADDITIONAL BENEFICIARY
 2 PROTECTIONS.—With respect to the offering of qualified
 3 prescription drug coverage by a MedicareAdvantage orga-
 4 nization under a MedicareAdvantage plan, the organiza-
 5 tion and plan shall meet the requirements of section
 6 1860D–5, including requirements relating to information
 7 dissemination and grievance and appeals, and such other
 8 requirements under part D that the Secretary determines
 9 appropriate in the same manner as such requirements
 10 apply to an eligible entity and a Medicare Prescription
 11 Drug plan under part D. The Secretary shall waive such
 12 requirements to the extent the Secretary determines that
 13 such requirements duplicate requirements otherwise appli-
 14 cable to the organization or the plan under this part.

15 “(c) PAYMENTS FOR PRESCRIPTION DRUGS.—

16 “(1) PAYMENT OF FULL AMOUNT OF PREMIUM
 17 TO ORGANIZATIONS FOR QUALIFIED PRESCRIPTION
 18 DRUG COVERAGE.— *Section 1860D–5(b)(1) of the Act*

19 “(A) IN GENERAL.—For each year (begin-
 20 ning with 2006), the Secretary shall pay to
 21 each MedicareAdvantage organization offering a
 22 MedicareAdvantage plan that provides qualified
 23 prescription drug coverage, an amount equal to
 24 the full amount of the monthly premium sub-
 25 mitted under section 1854(a)(2)(B) for the

1 year, as adjusted using the risk adjusters that
 2 apply to the standard prescription drug cov-
 3 erage published under section 1860D-11.

4 “(B) APPLICATION OF PART D RISK COR-
 5 RIDOR, STABILIZATION RESERVE FUND, AND
 6 ADMINISTRATIVE EXPENSES PROVISIONS.—The
 7 provisions of subsections (b), (c), and (d) of
 8 section 1860D-16 shall apply to a
 9 MedicareAdvantage organization offering a
 10 MedicareAdvantage plan that provides qualified
 11 prescription drug coverage and payments made
 12 to such organization under subparagraph (A) in
 13 the same manner as such provisions apply to an
 14 eligible entity offering a Medicare Prescription
 15 Drug plan and payments made to such entity
 16 under subsection (a) of section 1860D-16.

17 “(2) PAYMENT FROM PRESCRIPTION DRUG AC-
 18 COUNT.—Payment made to MedicareAdvantage or-
 19 ganizations under this subsection shall be made from
 20 the Prescription Drug Account in the Federal Sup-
 21plementary Medical Insurance Trust Fund under
 22 section 1841.

23 “(d) COMPUTATION OF MEDICAREADVANTAGE
 24 MONTHLY BENEFICIARY OBLIGATION FOR QUALIFIED
 25 PRESCRIPTION DRUG COVERAGE.—In the case of a

1 MedicareAdvantage eligible individual receiving qualified
2 prescription drug coverage under a MedicareAdvantage
3 plan during a year after 2005, the MedicareAdvantage
4 monthly beneficiary obligation for qualified prescription
5 drug coverage of such individual in the year shall be deter-
6 mined in the same manner as the monthly beneficiary obli-
7 gation is determined under section 1860D-17 for eligible
8 beneficiaries enrolled in a Medicare Prescription Drug
9 plan, except that, for purposes of this subparagraph, any
10 reference to the monthly plan premium approved by the
11 Secretary under section 1860D-13 shall be treated as a
12 reference to the monthly premium for qualified prescrip-
13 tion drug coverage submitted by the MedicareAdvantage
14 organization offering the plan under section
15 1854(a)(2)(A) and approved by the Secretary.

16 “(e) COLLECTION OF MEDICAREADVANTAGE
17 MONTHLY BENEFICIARY OBLIGATION FOR QUALIFIED
18 PRESCRIPTION DRUG COVERAGE.—The provisions of sec-
19 tion 1860D-18, including subsection (b) of such section,
20 shall apply to the amount of the MedicareAdvantage
21 monthly beneficiary obligation for qualified prescription
22 drug coverage (as determined under subsection (d)) re-
23 quired to be paid by a MedicareAdvantage eligible indi-
24 vidual enrolled in a MedicareAdvantage plan in the same
25 manner as such provisions apply to the amount of the

1 monthly beneficiary obligation required to be paid by an
 2 eligible beneficiary enrolled in a Medicare Prescription
 3 Drug plan under part D.

4 “(f) AVAILABILITY OF PREMIUM SUBSIDY AND COST-
 5 SHARING REDUCTIONS FOR LOW-INCOME ENROLLEES
 6 AND REINSURANCE PAYMENTS.—For provisions—

7 “(1) providing premium subsidies and cost-
 8 sharing reductions for low-income individuals receiv-
 9 ing qualified prescription drug coverage through a
 10 MedicareAdvantage plan, see section 1860D–19; and

11 “(2) providing a MedicareAdvantage organiza-
 12 tion with reinsurance payments for certain expenses
 13 incurred in providing qualified prescription drug cov-
 14 erage through a MedicareAdvantage plan, see sec-
 15 tion 1860D–20.”.

16 (b) TREATMENT OF REDUCTION FOR PURPOSES OF
 17 DETERMINING GOVERNMENT CONTRIBUTION UNDER
 18 PART B.—Section 1844(c) (42 U.S.C. 1395w) is amended
 19 by striking “section 1854(f)(1)(E)” and inserting “section
 20 1854(d)(1)(A)(i)”.

21 **SEC. 206. FACILITATING EMPLOYER PARTICIPATION.**

22 Section 1858(h) (as added by section 211) is amend-
 23 ed—

24 (1) by inserting “(including subsection (i) of
 25 such section)” after “section 1857”; and

(2) by adding at the end the following new sentence: “In applying the authority under section 1857(i) pursuant to this subsection, the Administrator may permit MedicareAdvantage plans to establish separate premium amounts for enrollees in an employer or other group health plan that provides employment-based retiree health coverage (as defined in section 1860D–20(d)(4)(B)).”

SEC. 207. ADMINISTRATION BY THE CENTER FOR MEDICARE CHOICES.

On and after January 1, 2006, the MedicareAdvantage program under part C of title XVIII of the Social Security Act shall be administered by the Center for Medicare Choices established under section 1808 such title (as added by section 301), and each reference to the Secretary made in such part shall be deemed to be a reference to the Administrator of the Center for Medicare Choices.

SEC. 208. CONFORMING AMENDMENTS.

(a) ORGANIZATIONAL AND FINANCIAL REQUIREMENTS FOR MEDICAREADVANTAGE ORGANIZATIONS; PROVIDER-SPONSORED ORGANIZATIONS.—Section 1855 (42 U.S.C. 1395w–25) is amended—

1 (1) in subsection (b), in the matter preceding
 2 paragraph (1), by inserting “subparagraphs (A),
 3 (B), and (D) of” before “section 1852(A)(1)”; and
 4 (2) by striking “Medicare+Choice” and insert-
 5 ing “MedicareAdvantage” each place it appears.

6 (b) ESTABLISHMENT OF PSO STANDARDS.—Section
 7 1856 (42 U.S.C. 1395w-26) is amended by striking
 8 “Medicare+Choice” and inserting “MedicareAdvantage”
 9 each place it appears.

10 (c) CONTRACTS WITH MEDICAREADVANTAGE ORGA-
 11 NIZATIONS.—Section 1857 (42 U.S.C. 1395w-27) is
 12 amended—

13 (1) in subsection (g)(1)—

14 (A) in subparagraph (B), by striking
 15 “amount of the Medicare+Choice monthly basic
 16 and supplemental beneficiary premiums” and
 17 inserting “amounts of the MedicareAdvantage
 18 monthly basic premium and MedicareAdvantage
 19 monthly beneficiary premium for enhanced
 20 medical benefits”;

21 (B) in subparagraph (F), by striking “or”
 22 after the semicolon at the end;

23 (C) in subparagraph (G), by adding “or”
 24 after the semicolon at the end; and

(D) by inserting after subparagraph (G) the following new subparagraph:

“(H)(i) charges any individual an amount in excess of the MedicareAdvantage monthly beneficiary obligation for qualified prescription drug coverage under section 1858A(d);

“(ii) provides coverage for prescription drugs that is not qualified prescription drug coverage;

“(iii) offers prescription drug coverage, but does not make standard prescription drug coverage available; or

“(iv) provides coverage for prescription drugs (other than that relating to prescription drugs covered under the original medicare fee-for-service program option described in section 1851(a)(1)(A)(i)) as an enhanced medical benefit under section 1852(a)(3)(D) or as an additional benefit under section 1854(g)(1)(F),”; and

(2) by striking “Medicare+Choice” and inserting “MedicareAdvantage” each place it appears.

(d) DEFINITIONS; MISCELLANEOUS PROVISIONS.—

Section 1859 (42 U.S.C. 1395w-28) is amended—

1 (1) by striking subsection (c) and inserting the
2 following new subsection:

3 “(c) OTHER REFERENCES TO OTHER TERMS.—

4 “(1) ENHANCED MEDICAL BENEFITS.—The
5 term ‘enhanced medical benefits’ is defined in sec-
6 tion 1852(a)(3)(E).

7 “(2) MEDICAREADVANTAGE ELIGIBLE INDI-
8 VIDUAL.—The term ‘MedicareAdvantage eligible in-
9 dividual’ is defined in section 1851(a)(3).

10 “(3) MEDICAREADVANTAGE PAYMENT AREA.—
11 The term ‘MedicareAdvantage payment area’ is de-
12 fined in section 1853(d).

13 “(4) NATIONAL PER CAPITA
14 MEDICARE+CHOICE GROWTH PERCENTAGE.—The
15 ‘national per capita Medicare+Choice growth per-
16 centage’ is defined in section 1853(c)(6).

17 “(5) MEDICAREADVANTAGE MONTHLY BASIC
18 BENEFICIARY PREMIUM; MEDICAREADVANTAGE
19 MONTHLY BENEFICIARY OBLIGATION FOR QUALI-
20 FIED PRESCRIPTION DRUG COVERAGE;
21 MEDICAREADVANTAGE MONTHLY BENEFICIARY PRE-
22 MIUM FOR ENHANCED MEDICAL BENEFITS.—The
23 terms ‘MedicareAdvantage monthly basic beneficiary
24 premium’, ‘MedicareAdvantage monthly beneficiary
25 obligation for qualified prescription drug coverage’,

and ‘MedicareAdvantage monthly beneficiary premium for enhanced medical benefits’ are defined in section 1854(b)(2).

“(6) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term ‘qualified prescription drug coverage’ has the meaning given such term in section 1860D(9).

“(7) STANDARD PRESCRIPTION DRUG COVERAGE.—The term ‘standard prescription drug coverage’ has the meaning given such term in section 1860D(10).”; and

(2) by striking “Medicare+Choice” and inserting “MedicareAdvantage” each place it appears.

(e) CONFORMING AMENDMENTS EFFECTIVE BEFORE 2006.—

(1) EXTENSION OF MSAs.—Section 1851(b)(4) (42 U.S.C. 1395w-21(b)(4)) is amended by striking “January 1, 2003” and inserting “January 1, 2004”.

(2) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT THROUGH 2005.—Section 1851(e) of the Social Security Act (42 U.S.C. 1395w-21(e)) is amended—

(A) in paragraph (2)(A), by striking “THROUGH 2004” and “December 31,2004” and

1 inserting “THROUGH 2005” and “December 31,
2 2005”, respectively;

3 (B) in the heading of paragraph (2)(B), by
4 striking “DURING 2005” and inserting “DURING
5 2006”;

6 (C) in paragraphs (2)(B)(i) and (2)(C)(i),
7 by striking “2005” and inserting “2006” each
8 place it appears;

9 (D) in paragraph (2)(D), by striking
10 “2004” and inserting “2005”; and

11 (E) in paragraph (4), by striking “2005”
12 and inserting “2006” each place it appears.

13 (3) UPDATE IN MINIMUM PERCENTAGE IN-
14 CREASE.—Section 1853(c)(1)(C) (42 U.S.C. 1395w-
15 23(c)(1)(C)) is amended by striking clause (iv) and
16 inserting the following new clauses:

17 “(iv) For 2002, 2003, and 2004, 102
18 percent of the annual Medicare+Choice
19 capitation rate under this paragraph for
20 the area for the previous year.

21 “(v) For 2005, 103 percent of the an-
22 nual Medicare+Choice capitation rate
23 under this paragraph for the area for
24 2003.

“(vi) For 2006 and each succeeding year, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year, except that such rate shall be determined by substituting ‘102’ for ‘103’ in clause (v).”.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date of enactment of this Act.

(e) OTHER CONFORMING AMENDMENTS.—

(1) CONFORMING MEDICARE CROSS-REFERENCES.—

(A) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by striking “section 1854(f)(1)(E)” and inserting “section 1854(g)(1)(C)(i)”. *CONFIRMED*

(B) Section 1840(i) (42 U.S.C. 1395s(i)) is amended by striking “section 1854(f)(1)(E)” and inserting “section 1854(g)(1)(C)(i)”.

(C) Section 1844(c) (42 U.S.C. 1395w(c)) is amended by striking “section 1854(f)(1)(E)” and inserting “section 1854(g)(1)(C)(i)”.

(D) Section 1876(k)(3)(A) (42 U.S.C. 1395mm(k)(3)(A)) is amended by inserting

“(as in effect immediately before the enactment of the Prescription Drug and Medicare Improvements Act of 2003)” after section 1853(a).

(F) Section 1876(k)(4) (42 U.S.C. 1395mm(k)(4)(A)) is amended—

(i) in subparagraph (A), by striking “section 1853(a)(3)(B)” and inserting “section 1853(a)(3)(D)”; and

(ii) in subparagraph (B), by striking “section 1854(g)” and inserting “section 1854(h)”.

(G) Section 1876(k)(4)(C) (42 U.S.C. 1395mm(k)(4)(C)) is amended by inserting “(as in effect immediately before the enactment of the Prescription Drug and Medicare Improvements Act of 2003)” after “section 1851(e)(6)”.

(H) Section 1894(d) (42 U.S.C. 1395eee(d)) is amended by adding at the end the following new paragraph:

“(3) APPLICATION OF PROVISIONS.—For purposes of paragraphs (1) and (2), the references to section 1853 and subsection (a)(2) of such section in such paragraphs shall be deemed to be references to

those provisions as in effect immediately before the enactment of the Prescription Drug and Medicare Improvements Act of 2003.”.

(2) CONFORMING MEDICARE TERMINOLOGY.— Title XVIII (42 U.S.C. 1395 et seq.), except for part C of such title (42 U.S.C. 1395w–21 et seq.), and title XIX (42 U.S.C. 1396 et seq.) are each amended by striking “Medicare+Choice” and inserting “MedicareAdvantage” each place it appears.

SEC. 209. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided in section 208(d)(3) and subsection (b), the amendments made by this title shall apply with respect to plan years beginning on and after January 1, 2006.

(b) MEDICAREADVANTAGE MSA PLANS.—Notwithstanding any provision of this title, the Secretary shall apply the payment and other rules that apply with respect to an MSA plan described in section 1851(a)(2)(B) of the Social Security Act (42 U.S.C. 1395w–21(a)(2)(B)) as if this title had not been enacted.

SEC. 210. IMPROVEMENTS IN MEDICAREADVANTAGE BENCHMARK DETERMINATIONS.

(a) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE

1 BENEFICIARIES IN CALCULATION OF
2 MEDICAREADVANTAGE PAYMENT RATES.—

3 (1) FOR PURPOSES OF CALCULATING
4 MEDICARE+CHOICE PAYMENT RATES.—Section
5 1853(c)(3) (42 U.S.C. 1395w-23(c)(3)), as amended
6 by section 203, is amended—

7 (A) in subparagraph (A), by striking “sub-
8 paragraph (B)” and inserting “subparagraphs
9 (B) and (E)”; and

10 (B) by adding at the end the following new
11 subparagraph:

12 “(E) INCLUSION OF COSTS OF DOD AND
13 VA MILITARY FACILITY SERVICES TO MEDICARE-
14 ELIGIBLE BENEFICIARIES.—In determining the
15 area-specific Medicare+Choice capitation rate
16 under subparagraph (A) for a year (beginning
17 with 2006), the annual per capita rate of pay-
18 ment for 1997 determined under section
19 1876(a)(1)(C) shall be adjusted to include in
20 the rate the Secretary’s estimate, on a per cap-
21 ita basis, of the amount of additional payments
22 that would have been made in the area involved
23 under this title if individuals entitled to benefits
24 under this title had not received services from

facilities of the Department of Defense or the Department of Veterans Affairs.”.

(2) FOR PURPOSES OF CALCULATING LOCAL FEE-FOR-SERVICE RATES.—Section 1853(d)(5) (42 U.S.C. 1395w-23(d)(5)), as amended by section 203, is amended—

(A) in subparagraph (A), by striking “subparagraph (B)” and inserting “subparagraphs (B) and (C)”; and

(B) by adding at the end the following new subparagraph:

“(C) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the local fee-for-service rate under subparagraph (A) for a year (beginning with 2006), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be adjusted to include in the rate the Secretary’s estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Depart-

1 ment of Defense or the Department of Veterans
2 Affairs.”.

3 (b) EFFECTIVE DATE.—The amendments made by
4 this section shall apply with respect to plan years begin-
5 ning on and after January 1, 2006.

6 **Subtitle B—Preferred Provider** 7 **Organizations**

8 **SEC. 211. ESTABLISHMENT OF MEDICAREADVANTAGE PRE-** 9 **ferred Provider Program Option.**

10 (a) ESTABLISHMENT OF PREFERRED PROVIDER
11 PROGRAM OPTION.—Section 1851(a)(2) is amended by
12 adding at the end the following new subparagraph:

13 “(D) PREFERRED PROVIDER ORGANIZA-
14 TION PLANS.—A MedicareAdvantage preferred
15 provider organization plan under the program
16 established under section 1858.”.

17 (b) PROGRAM SPECIFICATIONS.—Part C of title
18 XVIII (42 U.S.C. 1395w–21 et seq.) is amended by insert-
19 ing after section 1857 the following new section:

20 “PREFERRED PROVIDER ORGANIZATIONS

21 “SEC. 1858. (a) ESTABLISHMENT OF PROGRAM.—

22 “(1) IN GENERAL.—Beginning on January 1,
23 2006, there is established a preferred provider pro-
24 gram under which preferred provider organization
25 plans offered by preferred provider organizations are

1 offered to MedicareAdvantage eligible individuals in
2 preferred provider regions.

3 “(2) DEFINITIONS.—

4 “(A) PREFERRED PROVIDER ORGANIZA-
5 TION.—The term ‘preferred provider organiza-
6 tion’ means an entity with a contract under sec-
7 tion 1857 that meets the requirements of this
8 section applicable with respect to preferred pro-
9 vider organizations.

10 “(B) PREFERRED PROVIDER ORGANIZA-
11 TION PLAN.—The term ‘preferred provider or-
12 ganization plan’ means a MedicareAdvantage
13 plan that—

14 “(i) has a network of providers that
15 have agreed to a contractually specified re-
16 ~~imbursement~~ reimbursement for covered benefits with the
17 organization offering the plan;

18 “(ii) provides for reimbursement for
19 all covered benefits regardless of whether
20 such benefits are provided within such net-
21 work of providers; and

22 “(iii) is offered by a preferred pro-
23 vider organization.

24 “(C) PREFERRED PROVIDER REGION.—

25 The term ‘preferred provider region’ means—

1 “(i) a region established under para-
2 graph (3); and

3 “(ii) a region that consists of the en-
4 tire United States.

5 “(3) PREFERRED PROVIDER REGIONS.—For
6 purposes of this part the Secretary shall establish
7 preferred provider regions as follows:

8 “(A) There shall be at least 10 regions.

9 “(B) Each region must include at least 1
10 State.

11 “(C) The Secretary may not divide States
12 so that portions of the State are in different re-
13 gions.

14 “(D) To the extent possible, the Secretary
15 shall include multistate metropolitan statistical
16 areas in a single region. The Secretary may di-
17 vide metropolitan statistical areas where it is
18 necessary to establish regions of such size and
19 geography as to maximize the participation of
20 preferred provider organization plans.

21 “(E) The Secretary may conform the pre-
22 ferred provider regions to the service areas es-
23 tablished under section 1860D-10.

24 “(b) ELIGIBILITY, ELECTION, AND ENROLLMENT;
25 BENEFITS AND BENEFICIARY PROTECTIONS.—

1 “(1) IN GENERAL.—Except as provided in the
2 succeeding provisions of this subsection, the provi-
3 sions of sections 1851 and 1852 that apply with re-
4 spect to coordinated care plans shall apply to pre-
5 ferred provider organization plans offered by a pre-
6 ferred provider organization.

7 “(2) SERVICE AREA.—The service area of a
8 preferred provider organization plan shall be a pre-
9 ferred provider region.

10 “(3) AVAILABILITY.—Each preferred provider
11 organization plan must be offered to each
12 MedicareAdvantage eligible individual who resides in
13 the service area of the plan.

14 “(4) AUTHORITY TO PROHIBIT RISK SELEC-
15 TION.—The provisions of section 1852(a)(6) shall
16 apply to preferred provider organization plans.

17 “(5) ASSURING ACCESS TO SERVICES IN PRE-
18 ferred provider organization plans.—

19 “(A) IN GENERAL.—In addition to any
20 other requirements under this section, in the
21 case of a preferred provider organization plan,
22 the organization offering the plan must dem-
23 onstrate to the Secretary that the organization
24 has sufficient number and range of health care

1 professionals and providers willing to provide
2 services under the terms of the plan.

3 “(B) DETERMINATION OF SUFFICIENT AC-
4 CESS.—The Secretary shall find that an organi-
5 zation has met the requirement under subpara-
6 graph (A) with respect to any category of
7 health care professional or provider if, with re-
8 spect to that category of provider the plan has
9 contracts or agreements with a sufficient num-
10 ber and range of providers within such category
11 to provide covered services under the terms of
12 the plan.

13 “(C) CONSTRUCTION.—Subparagraph (B)
14 shall not be construed as restricting—

15 “(i) the persons from whom enrollees
16 under such plan may obtain covered bene-
17 fits; or

18 “(ii) the categories of licensed health
19 professionals or providers from whom en-
20 rollees under such a plan may obtain cov-
21 ered benefits if the covered services are
22 provided to enrollees in a State where 25
23 percent or more of the population resides
24 in health professional shortage areas des-

1 ignated pursuant to section 332 of the
2 Public Health Service Act.

3 “(c) PAYMENTS TO PREFERRED PROVIDER ORGANI-
4 ZATIONS.— ~~AMERICAN PREPARED FILE~~

5 “(1) PAYMENTS TO ORGANIZATIONS.—

6 “(A) MONTHLY PAYMENTS.—

7 ~~SECTION 1857~~“(i) IN GENERAL.—Under a contract
8 under section 1857 and subject to para-
9 graph (5), subsection (e), and section
10 1859(e)(4), the Secretary shall make, to
11 each preferred provider organization, with
12 respect to coverage of an individual for a
13 month under this part in a preferred pro-
14 vider region, separate monthly payments
15 with respect to—

16 ~~SECTION 1858~~“(I) benefits under the original
17 medicare fee-for-service program
18 under parts A and B in accordance
19 with paragraph (4); and

20 ~~SECTION 1858A~~“(II) benefits under the vol-
21 untary prescription drug program
22 under part D in accordance with sec-
23 tion 1858A and the other provisions
24 of this part.

1 “(ii) SPECIAL RULE FOR END-STAGE
2 RENAL DISEASE.—The Secretary shall es-
3 tablish separate rates of payment applica-
4 ble with respect to classes of individuals
5 determined to have end-stage renal disease
6 and enrolled in a preferred provider orga-
7 nization plan under this clause that are
8 similar to the separate rates of payment
9 described in section 1853(a)(1)(B).

10 “(B) ADJUSTMENT TO REFLECT NUMBER
11 OF ENROLLEES.—The Secretary may retro-
12 actively adjust the amount of payment under
13 this paragraph in a manner that is similar to
14 the manner in which payment amounts may be
15 retroactively adjusted under section 1853(a)(2).

16 “(C) COMPREHENSIVE RISK ADJUSTMENT
17 METHODOLOGY.—The Secretary shall apply the
18 comprehensive risk adjustment methodology de-
19 scribed in section 1853(a)(3)(B) to 100 percent
20 of the amount of payments to plans under para-
21 graph (4)(D)(ii).

22 “(D) ADJUSTMENT FOR SPENDING VARI-
23 ATIONS WITHIN A REGION.—The Secretary
24 shall establish a methodology for adjusting the
25 amount of payments to plans under paragraph

(4)(D)(ii) that achieves the same objective as the adjustment described in paragraph 1853(a)(2)(C).

“(2) ANNUAL CALCULATION OF BENCHMARK AMOUNTS FOR PREFERRED PROVIDER REGIONS.—

For each year (beginning in 2006), the Secretary shall calculate a benchmark amount for each preferred provider region for each month for such year with respect to coverage of the benefits available under the original medicare fee-for-service program option equal to the average of each benchmark amount calculated under section 1853(a)(4) for each MedicareAdvantage payment area for the year within such region, weighted by the number of MedicareAdvantage eligible individuals residing in each such payment area for the year.

“(3) ANNUAL ANNOUNCEMENT OF PAYMENT FACTORS.—

“(A) ANNUAL ANNOUNCEMENT.—Beginning in 2005, at the same time as the Secretary publishes the risk adjusters under section 1860D–11, the Secretary shall annually announce (in a manner intended to provide notice to interested parties) the following payment factors:

1 “(i) The benchmark amount for each
2 preferred provider region (as calculated
3 under paragraph (2)(A)) for the year.

4 “(ii) The factors to be used for ad-
5 justing payments described under—

6 “(I) the comprehensive risk ad-
7 justment methodology described in
8 paragraph (1)(C) with respect to each
9 preferred provider region for the year;
10 and

11 “(II) the methodology used for
12 adjustment for geographic variations
13 within such region established under
14 paragraph (1)(D).

15 “(B) ADVANCE NOTICE OF METHODO-
16 LOGICAL CHANGES.—At least 45 days before
17 making the announcement under subparagraph
18 (A) for a year, the Secretary shall—

19 “(i) provide for notice to preferred
20 provider organizations of proposed changes
21 to be made in the methodology from the
22 methodology and assumptions used in the
23 previous announcement; and

1 ~~provide~~“(ii) provide such organizations with
2 an opportunity to comment on such pro-
3 posed changes.

4 “(C) EXPLANATION OF ASSUMPTIONS.—In
5 each announcement made under subparagraph
6 (A), the Secretary shall include an explanation
7 of the assumptions and changes in methodology
8 used in the announcement in sufficient detail so
9 that preferred provider organizations can com-
10 pute each payment factor described in such
11 subparagraph.

12 “(4) SECRETARY’S DETERMINATION OF PAY-
13 MENT AMOUNT FOR BENEFITS UNDER THE ORIGI-
14 NAL MEDICARE FEE-FOR-SERVICE PROGRAM.—The
15 Secretary shall determine the payment amount for
16 plans as follows:

17 “(A) REVIEW OF PLAN BIDS.—The Sec-
18 retary shall review each plan bid submitted
19 under subsection (d)(1) for the coverage of ben-
20 efits under the original medicare fee-for-service
21 program option to ensure that such bids are
22 consistent with the requirements under this
23 part and are based on the assumptions de-
24 scribed in section 1854(a)(2)(A)(iii) that the

1 plan used with respect to numbers of enrolled
2 individuals.

3 “(B) DETERMINATION OF PREFERRED
4 PROVIDER REGIONAL BENCHMARK AMOUNTS.—

5 The Secretary shall calculate a preferred pro-
6 vider regional benchmark amount for that plan
7 for the benefits under the original medicare fee-
8 for-service program option for each plan equal
9 to the regional benchmark adjusted by using
10 the assumptions described in section
11 1854(a)(2)(A)(iii) that the plan used with re-
12 spect to numbers of enrolled individuals.

13 “(C) COMPARISON TO BENCHMARK.—The
14 Secretary shall determine the difference be-
15 tween each plan bid (as adjusted under sub-
16 paragraph (A)) and the preferred provider re-
17 gional benchmark amount (as determined under
18 subparagraph (B)) for purposes of deter-
19 mining—

20 “(i) the payment amount under sub-
21 paragraph (D); and

22 “(ii) the additional benefits required
23 and MedicareAdvantage monthly basic ben-
24 eficiary premiums.

1 “(D) DETERMINATION OF PAYMENT
2 AMOUNT.—

3 “(i) IN GENERAL.—Subject to clause
4 (ii), the Secretary shall determine the pay-
5 ment amount to a preferred provider orga-
6 nization for a preferred provider organiza-
7 tion plan as follows:

8 “(I) BIDS THAT EQUAL OR EX-
9 CEED THE BENCHMARK.—In the case
10 of a plan bid that equals or exceeds
11 ~~or is equal to~~ the preferred provider regional bench-
12 mark amount, the amount of each
13 ~~or is equal to~~ monthly payment to the organization
14 ~~or is equal to~~ with respect to each individual en-
15 rolled in a plan shall be the preferred
16 provider regional benchmark amount.

17 ~~or is equal to~~“(II) BIDS BELOW THE BENCH-
18 MARK.—In the case of a plan bid that
19 ~~or is equal to~~ is less than the preferred provider re-
20 gional benchmark amount, the
21 amount of each monthly payment to
22 the organization with respect to each
23 individual enrolled in a plan shall be
24 the preferred provider regional bench-
25 mark amount reduced by the amount

1 of any premium reduction elected by
2 the plan under section
3 1854(d)(1)(A)(i).

4 “(ii) APPLICATION OF ADJUSTMENT
5 METHODOLOGIES.—The Secretary shall ad-
6 just the amounts determined under sub-
7 paragraph (A) using the factors described
8 in paragraph (3)(A)(ii).

9 “(E) FACTORS USED IN ADJUSTING BIDS
10 AND BENCHMARKS FOR PREFERRED PROVIDER
11 ORGANIZATIONS AND IN DETERMINING EN-
12 ROLLEE PREMIUMS.—Subject to subparagraph
13 (F), in addition to the factors used to adjust
14 payments to plans described in section
15 1853(d)(6), the Secretary shall use the adjust-
16 ment for geographic variation within the region
17 established under paragraph (1)(D).

18 “(F) ADJUSTMENT FOR NATIONAL COV-
19 ERAGE DETERMINATIONS AND LEGISLATIVE
20 CHANGES IN BENEFITS.—The Secretary shall
21 provide for adjustments for national coverage
22 * determinations and legislative changes in bene-
23 fits applicable with respect to preferred provider
24 organizations in the same manner as the Sec-

retary provides for adjustments under section 1853(d)(7).

“(5) PAYMENTS FROM TRUST FUND.—The payment to a preferred provider organization under this section shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in a manner similar to the manner described in section 1853(g).

“(6) SPECIAL RULE FOR CERTAIN INPATIENT HOSPITAL STAYS.—Rules similar to the rules applicable under section 1853(h) shall apply with respect preferred provider organizations.

“(7) SPECIAL RULE FOR HOSPICE CARE.—Rules similar to the rules applicable under section 1853(i) shall apply with respect to preferred provider organizations.

“(d) SUBMISSION OF BIDS BY PPOs; PREMIUMS.—

“(1) SUBMISSION OF BIDS BY PREFERRED PROVIDER ORGANIZATIONS.—

“(A) IN GENERAL.—For the requirements on submissions by Medicare Advantage preferred provider organization plans, see section 1854(a)(1).

“(B) UNIFORM PREMIUMS.—Each bid amount submitted under subparagraph (A) for

1 a preferred provider organization plan in a pre-
2 ferred provider region may not vary among
3 MedicareAdvantage eligible individuals residing
4 in such preferred provider region.

5 “(C) APPLICATION OF FEHBP STANDARD;
6 PROHIBITION ON PRICE GOUGING.—Each bid
7 amount submitted under subparagraph (A) for
8 a preferred provider organization plan must
9 reasonably and equitably reflect the cost of ben-
10 efits provided under that plan.

11 “(D) REVIEW.—The Secretary shall review
12 the adjusted community rates (as defined in
13 section 1854(g)(3)), the amounts of the
14 MedicareAdvantage monthly basic premium and
15 the MedicareAdvantage monthly beneficiary
16 premium for enhanced medical benefits filed
17 under this paragraph and shall approve or dis-
18 approve such rates and amounts so submitted.
19 The Secretary shall review the actuarial as-
20 sumptions and data used by the preferred pro-
21 vider organization with respect to such rates
22 and amounts so submitted to determine the ap-
23 propriateness of such assumptions and data.

24 “(E) AUTHORITY TO LIMIT NUMBER OF
25 PLANS IN A REGION.—If there are bids for

1 more than 3 preferred provider organization
2 plans in a preferred provider region, the Sec-
3 retary shall accept only the 3 lowest-cost cred-
4 ible bids for that region that meet or exceed the
5 quality and minimum standards applicable
6 under this section.

7 “(2) MONTHLY PREMIUMS CHARGED.—The
8 amount of the monthly premium charged to an indi-
9 vidual enrolled in a preferred provider organization
10 plan offered by a preferred provider organization
11 shall be equal to the sum of the following:

12 “(A) The MedicareAdvantage monthly
13 basic beneficiary premium, as defined in section
14 1854(b)(2)(A) (if any).

15 “(B) The MedicareAdvantage monthly ben-
16 eficiary premium for enhanced medical benefits,
17 as defined in section 1854(b)(2)(C) (if any).

18 “(C) The MedicareAdvantage monthly obli-
19 gation for qualified prescription drug coverage,
20 as defined in section 1854(b)(2)(B) (if any).

21 “(3) DETERMINATION OF PREMIUM REDUC-
22 TIONS, REDUCED COST-SHARING, ADDITIONAL BENE-
23 FITS, AND BENEFICIARY PREMIUMS.—The rules for
24 determining premium reductions, reduced cost-shar-
25 ing, additional benefits, and beneficiary premiums

1 under section 1854(d) shall apply with respect to
2 preferred provider organizations.

3 “(4) PROHIBITION OF SEGMENTING PRE-
4 FERRED PROVIDER REGIONS.—The Secretary may
5 not permit a preferred provider organization to elect
6 to apply the provisions of this section uniformly to
7 separate segments of a preferred provider region
8 (rather than uniformly to an entire preferred pro-
9 vider region).

10 “(e) PORTION OF TOTAL PAYMENTS TO AN ORGANI-
11 ZATION SUBJECT TO RISK FOR 2 YEARS.—

12 “(1) NOTIFICATION OF SPENDING UNDER THE
13 PLAN.—

14 “(A) IN GENERAL.—For 2007 and 2008,
15 the preferred provider organization offering a
16 preferred provider organization plan shall notify
17 the Secretary of the total amount of costs that
18 the organization incurred in providing benefits
19 covered under parts A and B of the original
20 medicare fee-for-service program for all enroll-
21 ees under the plan in the previous year.

22 “(B) CERTAIN EXPENSES NOT IN-
23 CLUDED.—The total amount of costs specified
24 in subparagraph (A) may not include—

“(i) subject to subparagraph (C), administrative expenses incurred in providing the benefits described in such subparagraph; or

“(ii) amounts expended on providing enhanced medical benefits under section 1852(a)(3)(D).

“(C) ESTABLISHMENT OF ALLOWABLE ADMINISTRATIVE EXPENSES.—For purposes of applying subparagraph (B)(i), the administrative expenses incurred in providing benefits described in subparagraph (A) under a preferred provider organization plan may not exceed an amount determined appropriate by the Administrator.

“(2) ADJUSTMENT OF PAYMENT.—

“(A) NO ADJUSTMENT IF COSTS WITHIN RISK CORRIDOR.—If the total amount of costs specified in paragraph (1)(A) for the plan for the year are not more than the first threshold upper limit of the risk corridor (specified in paragraph (3)(A)(iii)) and are not less than the first threshold lower limit of the risk corridor (specified in paragraph (3)(A)(i)) for the plan for the year, then no additional payments shall

1 be made by the Secretary and no reduced pay-
2 ments shall be made to the preferred provider
3 organization offering the plan.

4 “(B) INCREASE IN PAYMENT IF COSTS
5 ABOVE UPPER LIMIT OF RISK CORRIDOR.—

6 “(i) IN GENERAL.—If the total
7 amount of costs specified in paragraph
8 (1)(A) for the plan for the year are more
9 than the first threshold upper limit of the
10 risk corridor for the plan for the year, then
11 the Secretary shall increase the total of the
12 monthly payments made to the preferred
13 provider organization offering the plan for
14 the year under subsection (c)(1)(A) by an
15 amount equal to the sum of—

16 “(I) 50 percent of the amount of
17 such total costs which are more than
18 such first threshold upper limit of the
19 risk corridor and not more than the
20 second threshold upper limit of the
21 risk corridor for the plan for the year
22 (as specified under paragraph
23 (3)(A)(iv)); and

24 “(II) 90 percent of the amount of
25 such total costs which are more than

such second threshold upper limit of
the risk corridor.

“(C) REDUCTION IN PAYMENT IF COSTS
BELOW LOWER LIMIT OF RISK CORRIDOR.—If
the total amount of costs specified in paragraph
(1)(A) for the plan for the year are less than
the first threshold lower limit of the risk cor-
ridor for the plan for the year, then the Sec-
retary shall reduce the total of the monthly pay-
ments made to the preferred provider organiza-
tion offering the plan for the year under sub-
section (c)(1)(A) by an amount (or otherwise
recover from the plan an amount) equal to—

“(i) 50 percent of the amount of such
total costs which are less than such first
threshold lower limit of the risk corridor
and not less than the second threshold
lower limit of the risk corridor for the plan
for the year (as specified under paragraph
(3)(A)(ii)); and

“(ii) 90 percent of the amount of such
total costs which are less than such second
threshold lower limit of the risk corridor.

“(3) ESTABLISHMENT OF RISK CORRIDORS.—

1 “(A) IN GENERAL.—For 2006 and 2007,
2 the Secretary shall establish a risk corridor for
3 each preferred provider organization plan. The
4 risk corridor for a plan for a year shall be equal
5 to a range as follows:

6 “(i) FIRST THRESHOLD LOWER
7 LIMIT.—The first threshold lower limit of
8 such corridor shall be equal to—

9 “(I) the target amount described
10 in subparagraph (B) for the plan;
11 minus

12 “(II) an amount equal to 5 per-
13 cent of such target amount.

14 “(ii) SECOND THRESHOLD LOWER
15 LIMIT.—The second threshold lower limit
16 of such corridor shall be equal to—

17 “(I) the target amount described
18 in subparagraph (B) for the plan;
19 minus

20 “(II) an amount equal to 10 per-
21 cent of such target amount.

22 “(iii) FIRST THRESHOLD UPPER
23 LIMIT.—The first threshold upper limit of
24 such corridor shall be equal to the sum
25 of—

“(I) such target amount; and
 “(II) the amount described in
 clause (i)(II).

“(iv) SECOND THRESHOLD UPPER
 LIMIT.—The second threshold upper limit
 of such corridor shall be equal to the sum
 of—

“(I) such target amount; and
 “(II) the amount described in
 clause (ii)(II).

“(B) TARGET AMOUNT DESCRIBED.—The
 target amount described in this paragraph is,
 with respect to a preferred provider organiza-
 tion plan offered by a preferred provider organi-
 zation in a year, an amount equal to the sum
 of—

“(i) the total monthly payments made
 to the organization for enrollees in the
 plan for the year under subsection
 (c)(1)(A); and

“(ii) the total Medicare Advantage
 basic beneficiary premiums collected for
 such enrollees for the year under sub-
 section (d)(2)(A).

1 “(4) PLANS AT RISK FOR ENTIRE AMOUNT OF
2 ENHANCED MEDICAL BENEFITS.—A preferred pro-
3 vider organization that offers a preferred provider
4 organization plan that provides enhanced medial
5 benefits under section 1852(a)(3)(D) shall be at full
6 financial risk for the provision of such benefits.

7 “(5) NO EFFECT ON ELIGIBLE BENE-
8 FICIARIES.—No change in payments made by reason
9 of this subsection shall affect the amount of the
10 MedicareAdvantage basic beneficiary premium that a
11 beneficiary is otherwise required to pay under the
12 plan for the year under subsection (d)(2)(A).

13 “(6) DISCLOSURE OF INFORMATION.—The pro-
14 visions of section 1860D–16(b)(7), including sub-
15 paragraph (B) of such section, shall apply to a pre-
16 ferred provider organization and a preferred pro-
17 vider organization plan in the same manner as such
18 provisions apply to an eligible entity and a Medicare
19 Prescription Drug plan under part D.

20 “(f) ORGANIZATIONAL AND FINANCIAL REQUIRE-
21 MENTS FOR PREFERRED PROVIDER ORGANIZATIONS.—A
22 preferred provider organization shall be organized and li-
23 censed under State law as a risk-bearing entity eligible
24 to offer health insurance or health benefits coverage in

1 each State within the preferred provider region in which
 2 it offers a preferred provider organization plan.

3 “(g) INAPPLICABILITY OF PROVIDER-SPONSORED
 4 ORGANIZATION SOLVENCY STANDARDS.—The require-
 5 ments of section 1856 shall not apply with respect to pre-
 6 ferred provider organizations.

7 “(h) CONTRACTS WITH PREFERRED PROVIDER OR-
 8 GANIZATIONS.—The provisions of section 1857 shall apply
 9 to a preferred provider organization plan offered by a pre-
 10 ferred provider organization under this section.”.

11 (c) PREFERRED PROVIDER TERMINOLOGY DE-
 12 FINED.—Section 1859(a) is amended by adding at the end
 13 the following new paragraph:

14 “(3) PREFERRED PROVIDER ORGANIZATION;
 15 PREFERRED PROVIDER ORGANIZATION PLAN; PRE-
 16 FERRED PROVIDER REGION.—The terms ‘preferred
 17 provider organization’, ‘preferred provider organiza-
 18 tion plan’, and ‘preferred provider region’ have the
 19 meaning given such terms in section 1858(a)(2).”.

20 **Subtitle C—Other Managed Care** 21 **Reforms**

22 **SEC. 221. EXTENSION OF REASONABLE COST CONTRACTS.**

23 (a) FIVE-YEAR EXTENSION.—Section 1876(h)(5)(C)
 24 (42 U.S.C. 1395mm(h)(5)(C)) is amended by striking
 25 “2004” and inserting “2009”.

1 (b) APPLICATION OF CERTAIN MEDICARE+CHOICE
 2 REQUIREMENTS TO COST CONTRACTS EXTENDED OR RE-
 3 NEWED AFTER 2003.—Section 1876(h) (42 U.S.C.
 4 1395mm(h)(5)), as amended by subsection (a), is amend-
 5 ed—

6 (1) by redesignating paragraph (5) as para-
 7 graph (6); and

8 (2) by inserting after paragraph (4) the fol-
 9 lowing new paragraph:

10 “(5) Any reasonable cost reimbursement contract
 11 with an eligible organization under this subsection that is
 12 extended or renewed on or after the date of enactment
 13 of the Prescription Drug and Medicare Improvements Act
 14 of 2003 for plan years beginning on or after January 1,
 15 2004, shall provide that the following provisions of the
 16 Medicare+Choice program under part C (and, on and
 17 after January 1, 2006, the provisions of the
 18 MedicareAdvantage program under such part) shall apply
 19 to such organization and such contract in a substantially
 20 similar manner as such provisions apply to
 21 Medicare+Choice organizations and Medicare+Choice
 22 plans (or, on and after January 1, 2006,
 23 MedicareAdvantage organizations and MedicareAdvantage
 24 plans, respectively) under such part:

1 “(A) Paragraph (1) of section 1852(e) (relating
2 to the requirement of having an ongoing quality as-
3 surance program) and paragraph (2)(B) of such sec-
4 tion (relating to the required elements for such a
5 program).

6 “(B) Section 1852(j)(4) (relating to limitations
7 on physician incentive plans).

8 “(C) Section 1854(c) (relating to the require-
9 ment of uniform premiums among individuals en-
10 rolled in the plan).

11 “(D) Section 1854(g), or, on and after January
12 1, 2006, section 1854(h) (relating to restrictions on
13 imposition of premium taxes with respect to pay-
14 ments to organizations).

15 “(E) Section 1856(b) (regarding compliance
16 with the standards established by regulation pursu-
17 ant to such section, including the provisions of para-
18 graph (3) of such section relating to relation to
19 State laws).

20 “(F) Section 1852(a)(3)(A) (regarding the au-
21 thority of organizations to include supplemental
22 health care benefits and, on and after January 1,
23 2006, enhanced medical benefits under the plan sub-
24 ject to the approval of the Secretary).

1 “(G) The provisions of part C relating to
2 timelines for benefit filings, contract renewal, and
3 beneficiary notification.

4 “(H) Section 1854(e), or, on and after January
5 1, 2006, section 1854(f) (relating to proposed cost-
6 sharing under the contract being subject to review
7 by the Secretary).”.

8 (c) PERMITTING DEDICATED GROUP PRACTICE
9 HEALTH MAINTENANCE ORGANIZATIONS TO PARTICI-
10 PATE IN THE MEDICARE COST CONTRACT PROGRAM.—
11 Section 1876(h)(6) of the Social Security Act (42 U.S.C.
12 1395mm(h)(6)), as redesignated and amended by sub-
13 sections (a) and (b), is amended—

14 (1) in subparagraph (A), by striking “After the
15 date of the enactment” and inserting “Except as
16 provided in subparagraph (C), after the date of the
17 enactment”;

18 (2) in subparagraph (B), by striking “subpara-
19 graph (C)” and inserting “subparagraph (D)”;

20 (3) by redesignating subparagraph (C) as sub-
21 paragraph (D); and

22 (4) by inserting after subparagraph (B), the
23 following new subparagraph:

1 “(C) Subject to paragraph (5) and subparagraph
2 (D), the Secretary shall approve an application to enter
3 into a reasonable cost contract under this section if—

4 “(i) the application is submitted to the Sec-
5 retary by a health maintenance organization (as de-
6 fined in section 1301(a) of the Public Health Service
7 Act) that, as of January 1, 2004, and except as pro-
8 vided in section 1301(b)(3)(B) of such Act, provides
9 at least 85 percent of the services of a physician
10 which are provided as basic health services through
11 a medical group (or groups), as defined in section
12 1302(4) of such Act; and

13 “(ii) the Secretary determines that the organi-
14 zation meets the requirements applicable to such or-
15 ganizations and contracts under this section.”.

16 **SEC. 222. SPECIALIZED MEDICARE+CHOICE PLANS FOR**
17 **SPECIAL NEEDS BENEFICIARIES.**

18 (a) TREATMENT AS COORDINATED CARE PLAN.—
19 Section 1851(a)(2)(A) (42 U.S.C. 1395w-21(a)(2)(A)) is
20 amended by adding at the end the following new sentence:
21 “Specialized Medicare+Choice plans for special needs
22 beneficiaries (as defined in section 1859(b)(4)) may be
23 any type of coordinated care plan.”.

24 (b) SPECIALIZED MEDICARE+CHOICE PLAN FOR
25 SPECIAL NEEDS BENEFICIARIES DEFINED.—Section

1 1859(b) (42 U.S.C. 1395w-28(b)) is amended by adding
 2 at the end the following new paragraph:

3 “(4) SPECIALIZED MEDICARE+CHOICE PLANS
 4 FOR SPECIAL NEEDS BENEFICIARIES.—

5 “(A) IN GENERAL.—The term ‘specialized
 6 Medicare+Choice plans for special needs bene-
 7 ficiaries’ means a Medicare+Choice plan that—

8 “(i) exclusively serves special needs
 9 beneficiaries (as defined in subparagraph
 10 (B)), or

11 “(ii) to the extent provided in regula-
 12 tions prescribed by the Secretary, dis-
 13 proportionately serves such special needs
 14 beneficiaries, frail elderly medicare bene-
 15 ficiaries, or both.

16 “(B) SPECIAL NEEDS BENEFICIARY.—The
 17 term ‘special needs beneficiary’ means a
 18 Medicare+Choice eligible individual who—

19 “(i) is institutionalized (as defined by
 20 the Secretary);

21 “(ii) is entitled to medical assistance
 22 under a State plan under title XIX; or

23 “(iii) meets such requirements as the
 24 Secretary may determine would benefit
 25 from enrollment in such a specialized

Medicare+Choice plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.”.

(c) RESTRICTION ON ENROLLMENT PERMITTED.—

Section 1859 (42 U.S.C. 1395w-28) is amended by adding at the end the following new subsection:

“(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare+Choice plan (as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2008, the plan may restrict the enrollment of individuals under the plan to individuals who are within 1 or more classes of special needs beneficiaries.”.

(d) REPORT TO CONGRESS.—Not later than December

31, 2006, the Secretary shall submit to Congress a report that assesses the impact of specialized Medicare+Choice plans for special needs beneficiaries on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made by subsections (a), (b), and (c).

(e) EFFECTIVE DATES.—

1 (1) IN GENERAL.—The amendments made by
2 subsections (a), (b), and (c) shall take effect on the
3 date of enactment of this Act.

4 (2) DEADLINE FOR ISSUANCE OF REQUIRE-
5 MENTS FOR SPECIAL NEEDS BENEFICIARIES; TRAN-
6 SITION.—No later than 1 year after the date of en-
7 actment of this Act, the Secretary shall issue final
8 regulations to establish requirements for special
9 needs beneficiaries under section 1859(b)(4)(B)(iii)
10 of the Social Security Act, as added by subsection
11 (b).

12 **SEC. 223. PAYMENT BY PACE PROVIDERS FOR MEDICARE**
13 **AND MEDICAID SERVICES FURNISHED BY**
14 **NONCONTRACT PROVIDERS.**

15 (a) MEDICARE SERVICES.—

16 (1) MEDICARE SERVICES FURNISHED BY PRO-
17 VIDERS OF SERVICES.—Section 1866(a)(1)(O) (42
18 U.S.C. 1395cc(a)(1)(O)) is amended—

19 (A) by striking “part C or” and inserting
20 “part C, with a PACE provider under section
21 1894 or 1934, or”;

22 (B) by striking “(i)”;

23 (C) by striking “and (ii)”;

24 (D) by striking “members of the organiza-
25 tion” and inserting “members of the organiza-

tion or PACE program eligible individuals enrolled with the PACE provider,”.

(2) MEDICARE SERVICES FURNISHED BY PHYSICIANS AND OTHER ENTITIES.—Section 1894(b) (42 U.S.C. 1395eee(b)) is amended by adding at the end the following new paragraphs:

“(3) TREATMENT OF MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—

“(A) APPLICATION OF MEDICARE+CHOICE REQUIREMENT WITH RESPECT TO MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—Section 1852(k)(1) (relating to limitations on balance billing against Medicare+Choice organizations for noncontract physicians and other entities with respect to services covered under this title) shall apply to PACE providers, PACE program eligible individuals enrolled with such PACE providers, and physicians and other entities that do not have a contract establishing payment amounts for services furnished to such an individual in the same manner as such section applies to Medicare+Choice organizations, individuals enrolled with such organizations, and

1 physicians and other entities referred to in such
2 section.

3 “(B) REFERENCE TO RELATED PROVISION
4 FOR NONCONTRACT PROVIDERS OF SERVICES.—
5 For the provision relating to limitations on bal-
6 ance billing against PACE providers for serv-
7 ices covered under this title furnished by non-
8 contract providers of services, see section
9 1866(a)(1)(O).

10 “(4) REFERENCE TO RELATED PROVISION
11 FOR SERVICES COVERED UNDER TITLE XIX BUT
12 NOT UNDER THIS TITLE.—For provisions relat-
13 ing to limitations on payments to providers par-
14 ticipating under the State plan under title XIX
15 that do not have a contract with a PACE pro-
16 vider establishing payment amounts for services
17 covered under such plan (but not under this
18 title) when such services are furnished to enroll-
19 ees of that PACE provider, see section
20 1902(a)(66).”.

21 (b) MEDICAID SERVICES.—

22 (1) REQUIREMENT UNDER STATE PLAN.—Sec-
23 tion 1902(a) (42 U.S.C. 1396a(a)) is amended—

24 (A) in paragraph (64), by striking “and”
25 at the end;

1 (B) in paragraph (65), by striking the pe-
2 riod at the end and inserting “; and”; and

3 ~~§ 65~~ (C) by inserting after paragraph (65) the
4 following new paragraph:

5 “(66) provide, with respect to services cov-
6 ered under the State plan (but not under title
7 XVIII) that are furnished to a PACE program
8 eligible individual enrolled with a PACE pro-
9 vider by a provider participating under the
10 State plan that does not have a contract with
11 the PACE provider that establishes payment
12 amounts for such services, that such partici-
13 pating provider may not require the PACE pro-
14 vider to pay the participating provider an
15 amount greater than the amount that would
16 otherwise be payable for the service to the par-
17 ticipating provider under the State plan for the
18 State where the PACE provider is located (in
19 accordance with regulations issued by the Sec-
20 retary).”.

21 (2) REFERENCE IN MEDICAID STATUTE.—Sec-
22 tion 1934(b) (42 U.S.C. 1396u-4(b)) is amended by
23 adding at the end the following new paragraphs:

1 “(3) TREATMENT OF MEDICARE SERVICES FUR-
2 NISHED BY NONCONTRACT PHYSICIANS AND OTHER
3 ENTITIES.—

4 “(A) APPLICATION OF MEDICARE+CHOICE
5 REQUIREMENT WITH RESPECT TO MEDICARE
6 SERVICES FURNISHED BY NONCONTRACT PHY-
7 SICIANS AND OTHER ENTITIES.—Section
8 1852(k)(1) (relating to limitations on balance
9 billing against Medicare+Choice organizations
10 for noncontract physicians and other entities
11 with respect to services covered under title
12 XVIII) shall apply to PACE providers, PACE
13 program eligible individuals enrolled with such
14 PACE providers, and physicians and other enti-
15 ties that do not have a contract establishing
16 payment amounts for services furnished to such
17 an individual in the same manner as such sec-
18 tion applies to Medicare+Choice organizations,
19 individuals enrolled with such organizations,
20 and physicians and other entities referred to in
21 such section.

22 “(B) REFERENCE TO RELATED PROVISION
23 FOR NONCONTRACT PROVIDERS OF SERVICES.—
24 For the provision relating to limitations on bal-
25 ance billing against PACE providers for serv-

ices covered under title XVIII furnished by non-
 contract providers of services, see section
 1866(a)(1)(O).

“(4) REFERENCE TO RELATED PROVISION
 FOR SERVICES COVERED UNDER THIS TITLE
 BUT NOT UNDER TITLE XVIII.—For provisions
 relating to limitations on payments to providers
 participating under the State plan under this
 title that do not have a contract with a PACE
 provider establishing payment amounts for serv-
 ices covered under such plan (but not under
 title XVIII) when such services are furnished to
 enrollees of that PACE provider, see section
 1902(a)(66).”

(c) EFFECTIVE DATE.—The amendments made by
 this section shall apply to services furnished on or after
 January 1, 2004.

**SEC. 224. INSTITUTE OF MEDICINE EVALUATION AND RE-
 PORT ON HEALTH CARE PERFORMANCE
 MEASURES.**

(a) EVALUATION.—

(1) IN GENERAL.—Not later than the date that
 is 2 months after the date of enactment of this Act,
 the Secretary of Health and Human Services shall
 enter into an arrangement under which the Institute

1 of Medicine of the National Academy of Sciences (in
2 this section referred to as the “Institute”) shall con-
3 duct an evaluation of leading health care perform-
4 ance measures and options to implement policies
5 that align performance with payment under the
6 medicare program under title XVIII of the Social
7 Security Act (42 U.S.C. 1395 et seq.).

8 (2) SPECIFIC MATTERS EVALUATED.—In con-
9 ducting the evaluation under paragraph (1), the In-
10 stitute shall—

11 (A) catalogue, review, and evaluate the va-
12 lidity of leading health care performance meas-
13 ures;

14 (B) catalogue and evaluate the success and
15 utility of alternative performance incentive pro-
16 grams in public or private sector settings; and

17 (C) identify and prioritize options to imple-
18 ment policies that align performance with pay-
19 ment under the medicare program that indi-
20 cate—

21 (i) the performance measurement set
22 to be used and how that measurement set
23 will be updated;

24 (ii) the payment policy that will re-
25 ward performance; and

(iii) the key implementation issues
(such as data and information technology
requirements) that must be addressed.

(3) SCOPE OF HEALTH CARE PERFORMANCE
MEASURES.—The health care performance measures
described in paragraph (2)(A) shall encompass a variety of perspectives, including physicians, hospitals, health plans, purchasers, and consumers.

(4) CONSULTATION WITH MEDPAC.—In evaluating the matters described in paragraph (2)(C), the Institute shall consult with the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6).

(b) REPORT.—Not later than the date that is 18 months after the date of enactment of this Act, the Institute shall submit to the Secretary of Health and Human Services, the Committees on Ways and Means and Energy and Commerce of the House of Representatives, and the Committee on Finance of the Senate a report on the evaluation conducted under subsection (a)(1) describing the findings of such evaluation and recommendations for an overall strategy and approach for aligning payment with performance in the original medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act, the Medicare+Choice program under part

1 C of such title, and any other programs under such title
2 XVIII.

3 (c) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated \$1,000,000 for purposes
5 of conducting the evaluation and preparing the report re-
6 quired by this section.

7 **SEC. 225. EXPANDING THE WORK OF MEDICARE QUALITY**
8 **IMPROVEMENT ORGANIZATIONS TO INCLUDE**
9 **PARTS C AND D.**

10 (a) APPLICATION TO MEDICARE MANAGED CARE
11 AND PRESCRIPTION DRUG COVERAGE.—Section
12 1154(a)(1) (42 U.S.C. 1320c-3(a)(1)) is amended by in-
13 serting “, Medicare+Choice organizations and
14 MedicareAdvantage organizations under part C, and pre-
15 scription drug card sponsors and eligible entities under
16 part D” after “under section 1876”.

17 (b) PRESCRIPTION DRUG THERAPY QUALITY IM-
18 PROVEMENT.—Section 1154(a) (42 U.S.C. 1320c-3(a)) is
19 amended by adding at the end the following new para-
20 graph:

21 “(17) The organization shall execute its respon-
22 sibilities under subparagraphs (A) and (B) of para-
23 graph (1) by offering to providers, practitioners, pre-
24 scription drug card sponsors and eligible entities
25 under part D, and Medicare+Choice and

MedicareAdvantage plans under part C quality improvement assistance pertaining to prescription drug therapy. For purposes of this part and title XVIII, the functions described in this paragraph shall be treated as a review function.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply on and after January 1, 2004.

**SEC. 226. EXTENSION OF DEMONSTRATION FOR ESRD MAN-
AGED CARE.**

The Secretary shall extend without interruption, through December 31, 2007, the approval of the demonstration project, Contract No. H1021, under the authority of section 2355(b)(1)(B)(iv) of the Deficit Reduction Act of 1984, as amended by section 13567 of the Omnibus Reconciliation Act of 1993. Such approval shall be subject to the terms and conditions in effect for the 2002 project year with respect to eligible participants and covered benefits. The Secretary shall set the monthly capitation rate for enrollees on the basis of the reasonable medical and direct administrative costs of providing those benefits to such participants.

1 **Subtitle D—Evaluation of Alter-**
 2 **native Payment and Delivery**
 3 **Systems**

4 **SEC. 231. ESTABLISHMENT OF ALTERNATIVE PAYMENT**
 5 **SYSTEM FOR PREFERRED PROVIDER ORGA-**
 6 **NIZATIONS IN HIGHLY COMPETITIVE RE-**
 7 **GIONS.**

8 (a) ESTABLISHMENT OF ALTERNATIVE PAYMENT
 9 SYSTEM FOR PREFERRED PROVIDER ORGANIZATIONS IN
 10 HIGHLY COMPETITIVE REGIONS.—Section 1858 (as
 11 added by section 211(b)) is amended by adding at the end
 12 the following new subsection:

13 “(i) ALTERNATIVE PAYMENT METHODOLOGY FOR
 14 HIGHLY COMPETITIVE REGIONS.—

15 “(1) ANNUAL DETERMINATION AND DESIGNA-
 16 TION.—

17 “(A) IN 2008.—In 2008, prior to the date
 18 on which the Secretary expects to publish the
 19 risk adjusters under section 1860D–11, the
 20 Secretary shall designate a limited number (but
 21 in no case fewer than 1) of preferred provider
 22 regions (other than the region described in sub-
 23 section (a)(2)(C)(ii)) as highly competitive re-
 24 gions.

1 “(B) SUBSEQUENT YEARS.—For each year
2 (beginning with 2009) the Secretary may des-
3 ignate a limited number of preferred provider
4 regions (other than the region described in sub-
5 section (a)(2)(C)(ii)) as highly competitive re-
6 gions in addition to any region designated as a
7 highly competitive region under subparagraph
8 (A).

9 “(C) CONSIDERATIONS.—In determining
10 which preferred provider regions to designate as
11 highly competitive regions under subparagraph
12 (A) or (B), the Secretary shall consider the fol-
13 lowing:

14 “(i) Whether the application of this
15 subsection to the preferred provider region
16 would enhance the participation of pre-
17 ferred provider organization plans in that
18 region.

19 “(ii) Whether the Secretary antici-
20 pates that there is likely to be at least 3
21 bids submitted under subsection (d)(1)
22 with respect to the preferred provider re-
23 gion if the Secretary designates such re-
24 gion as a highly competitive region under
25 subparagraph (A) or (B).

1 “(iii) Whether the Secretary expects
 2 that MedicareAdvantage eligible individuals
 3 will elect preferred provider organization
 4 plans in the preferred provider region if
 5 the region is designated as a highly com-
 6 petitive region under subparagraph (A) or
 7 (B).

8 “(iv) Whether the designation of the
 9 preferred provider region as a highly com-
 10 petitive region will permit compliance with
 11 the limitation described in paragraph (5).

12 In considering the matters described in clauses
 13 (i) through (iv), the Secretary shall give special
 14 consideration to preferred provider regions
 15 where no bids were submitted under subsection
 16 (d)(1) for the previous year.

17 “(2) EFFECT OF DESIGNATION.—If a preferred
 18 provider region is designated as a highly competitive
 19 region under subparagraph (A) or (B) of paragraph
 20 (1)—

21 “(A) the provisions of this subsection shall
 22 * apply to such region and shall supersede the
 23 provisions of this part relating to benchmarks
 24 for preferred provider regions; and

1 “(B) such region shall continue to be a
2 highly competitive region until such designation
3 is rescinded pursuant to paragraph (5)(B)(ii).

4 “(3) SUBMISSION OF BIDS.—

5 “(A) IN GENERAL.—Notwithstanding sub-
6 section (d)(1), for purposes of applying section
7 1854(a)(2)(A)(i), the plan bid for a highly com-
8 petitive region shall consist of a dollar amount
9 that represents the total amount that the plan
10 is willing to accept (not taking into account the
11 application of the comprehensive risk adjust-
12 ment methodology under section 1853(a)(3))
13 for providing coverage of only the benefits de-
14 scribed in section 1852(a)(1)(A) to an indi-
15 vidual enrolled in the plan that resides in the
16 service area of the plan for a month.

17 “(B) CONSTRUCTION.—Nothing in sub-
18 paragraph (A) shall be construed as permitting
19 a preferred provider organization plan not to
20 provide coverage for the benefits described in
21 section 1852(a)(1)(C).

22 “(4) PAYMENTS TO PREFERRED PROVIDER OR-
23 GANIZATIONS IN HIGHLY COMPETITIVE AREAS.—

24 With respect to highly competitive regions, the fol-
25 lowing rules shall apply:

1 “(A) IN GENERAL.—Notwithstanding sub-
 2 section (c), of the plans described in subsection
 3 (d)(1)(E), the Secretary shall substitute the
 4 second lowest bid for the benchmark applicable
 5 under subsection (c)(4).

6 “(B) IF THERE ARE FEWER THAN THREE
 7 BIDS.—Notwithstanding subsection (c), if there
 8 are fewer than 3 bids in a highly competitive
 9 region for a year, the Secretary shall substitute
 10 the lowest bid for the benchmark applicable
 11 under subsection (c)(4).

12 “(5) FUNDING LIMITATION.—

13 “(A) IN GENERAL.—

14 “(i) IN GENERAL.—The total amount
 15 expended as a result of the application of
 16 this subsection during the period or year,
 17 as applicable, may not exceed the applica-
 18 ble amount (as defined in clause (ii)).

19 “(ii) APPLICABLE AMOUNT DE-
 20 FINED.—In this paragraph, the term ‘ap-
 21 plicable amount’ means—

22 “(I) for the period beginning on
 23 January 1, 2009, and ending on Sep-
 24 tember 30, 2013, the total amount
 25 that would have been expended under

1 this title during the period if this sub-
 2 section had not been enacted plus
 3 that title \$6,000,000,000; and
 4 read “(II) for fiscal year 2014 and
 5 thereafter any subsequent fiscal year, the total
 6 amount that would have been ex-
 7 penditures under this title during the
 8 year if this subsection had not been
 9 enacted.

10 “(B) APPLICATION OF LIMITATION.—If
 11 the Secretary determines that the application of
 12 this subsection will cause expenditures to exceed
 13 the applicable amount, the Secretary shall—

14 “(i) take appropriate steps to stay
 15 within the applicable amount, including
 16 through providing limitations on enroll-
 17 ment; or

18 “(ii) rescind the designation under
 19 subparagraph (A) or (B) of paragraph (1)
 20 of 1 or more preferred provider regions as
 21 highly competitive regions.

22 “(C) TRANSITION.—If the Secretary re-
 23 scinds a designation under subparagraph (A) or
 24 (B) of paragraph (1) pursuant to subparagraph
 25 (B)(ii) with respect to a preferred provider re-

1 gion, the Secretary shall provide for an appro-
2 prium transition from the payment system ap-
3 plicable under this subsection to the payment
4 system described in the other provisions of this
5 section in that region. Any amount expended by
6 reason of the preceding sentence shall be con-
7 sidered to be part of the total amount expended
8 as a result of the application of this subsection
9 for purposes of applying the limitation under
10 subparagraph (A).

11 “(D) APPLICATION.—Notwithstanding
12 paragraph (1)(B), on or after January 1 of the
13 year in which the fiscal year described in sub-
14 paragraph (A)(ii)(II) begins, the Secretary may
15 designate appropriate regions under such para-
16 graph.

17 “(6) LIMITATION OF JUDICIAL REVIEW.—There
18 shall be no administrative or judicial review under
19 section 1869, section 1878, or otherwise, of designa-
20 tions made under subparagraph (A) or (B) of para-
21 graph (1).

22 “(7) SECRETARY REPORTS.—Not later than
23 April 1 of each year (beginning in 2010), the Sec-
24 retary shall submit a report to Congress and the

1 Comptroller General of the United States that in-
2 cludes—

3 “(A) a detailed description of—

4 “(i) the total amount expended as a
5 result of the application of this subsection
6 in the previous year compared to the total
7 amount that would have been expended
8 under this title in the year if this sub-
9 section had not been enacted;

10 “(ii) the projections of the total
11 amount that will be expended as a result
12 of the application of this subsection in the
13 year in which the report is submitted com-
14 pared to the total amount that would have
15 been expended under this title in the year
16 if this subsection had not been enacted;

17 “(iii) amounts remaining within the
18 funding limitation specified in paragraph
19 (5); and

20 “(iv) the steps that the Secretary will
21 take under clauses (i) and (ii) of para-
22 graph (5)(B) to ensure that the application
23 of this subsection will not cause expendi-
24 tures to exceed the applicable amount de-
25 scribed in paragraph (5)(A); and

1 “(B) a certification from the Chief Actuary
 2 of the Centers for Medicare & Medicaid Serv-
 3 ices that the descriptions under clauses (i), (ii),
 4 (iii), and (iv) of subparagraph (A) are reason-
 5 able, accurate, and based on generally accepted
 6 actuarial principles and methodologies.

7 “(8) BIENNIAL GAO REPORTS.—Not later than
 8 January 1, 2011, and biennially thereafter, the
 9 Comptroller General of the United States shall sub-
 10 mit to the Secretary and Congress a report on the
 11 designation of highly competitive regions under this
 12 subsection and the application of the payment sys-
 13 tem under this subsection within such regions. Each
 14 report shall include—

15 “(A) an evaluation of—

16 “(i) the quality of care provided to
 17 beneficiaries enrolled in a
 18 MedicareAdvantage preferred provider plan
 19 in a highly competitive region;

20 “(ii) the satisfaction of beneficiaries
 21 with benefits under such a plan;

22 “(iii) the costs to the medicare pro-
 23 gram for payments made to such plans;
 24 and

“(iv) any improvements in the delivery
of health care services under such a plan;

“(B) a comparative analysis of the benchmark system applicable under the other provisions of this section and the payment system applicable in highly competitive regions under this subsection; and

“(C) recommendations for such legislation or administrative action as the Comptroller General determines to be appropriate.

“(9) REPORT ON BUDGET NEUTRALITY FOR FISCAL YEARS AFTER 2013.—

“(A) IN GENERAL.—If the Secretary intends to designate 1 or more regions as highly competitive regions with respect to calendar 2014 or any subsequent calendar year, the Secretary shall submit a report to Congress indicating such intent no later than April 1 of the calendar year prior to the calendar year in which the applicable designation year begins.

“(B) REQUIREMENTS.—A report submitted under subparagraph (A) shall—

“(i) specify the steps (if any) that the Secretary will take pursuant to paragraph (5)(B) to ensure that the total amount ex-

1 pended as a result of the application of
 2 this subsection during the year will not ex-
 3 ceed the applicable amount for the year (as
 4 defined in paragraph (5)(A)(ii)(II)); and
 5 “(ii) contain a certification from the
 6 Chief Actuary of the Centers for Medicare
 7 and Medicaid Services that such steps will
 8 meet the requirements of paragraph (5)(A)
 9 based on an analysis using generally ac-
 10 cepted actuarial principles and methodolo-
 11 gies.”.

12 (b) CONFORMING AMENDMENT.—Section
 13 1858(c)(3)(A)(i) (as added by section 211(b)) is amended
 14 to read as follows:

15 “(i) Whether each preferred provider
 16 region has been designated as a highly
 17 competitive region under subparagraph (A)
 18 or (B) of subsection (i)(1) and the bench-
 19 mark amount for any preferred provider
 20 region (as calculated under paragraph
 21 (2)(A)) for the year that has not been des-
 22 ignated as a highly competitive region.”.

23 **SEC. 232. FEE-FOR-SERVICE MODERNIZATION PROJECTS.**

24 (a) ESTABLISHMENT.—

1 (1) REVIEW AND REPORT ON RESULTS OF EX-
2 ISTING DEMONSTRATIONS.—

3 ~~and~~ (A) REVIEW.—The Secretary shall conduct
4 an empirical review of the results of the dem-
5 onstrations under sections 442, 443, and 444.

6 (B) REPORT.—Not later than January 1,
7 2008, the Secretary shall submit a report to
8 Congress on the empirical review conducted
9 under subparagraph (A) which shall include es-
10 timates of the total costs of the demonstrations,
11 including expenditures as a result of the provi-
12 sion of services provided to beneficiaries under
13 the demonstrations that are incidental to the
14 services provided under the demonstrations, and
15 all other expenditures under title XVIII of the
16 Social Security Act. The report shall also in-
17 clude a certification from the Chief Actuary of
18 the Centers for Medicare & Medicaid Services
19 that such estimates are reasonable, accurate,
20 and based on generally accepted actuarial prin-
21 ciples and methodologies.

22 (2) PROJECTS.—Beginning in 2009, the Sec-
23 retary, based on the empirical review conducted
24 under paragraph (1), shall establish projects under
25 which medicare beneficiaries receiving benefits under

1 the medicare fee-for-service program under parts A
2 and B of title XVIII of the Social Security Act are
3 provided with coverage of enhanced benefits or serv-
4 ices under such program. The purpose of such
5 projects is to evaluate whether the provision of such
6 enhanced benefits or services to such beneficiaries—

7 (A) improves the quality of care provided
8 to such beneficiaries under the medicare pro-
9 gram;

10 (B) improves the health care delivery sys-
11 tem under the medicare program; and

12 (C) results in reduced expenditures under
13 the medicare program.

14 (2) ENHANCED BENEFITS OR SERVICES.—For
15 purposes of this section, enhanced benefits or serv-
16 ices shall include—

17 (A) preventive services not otherwise cov-
18 ered under title XVIII of the Social Security
19 Act;

20 (B) chronic care coordination services;

21 (C) disease management services; or

22 (D) other benefits or services that the Sec-
23 retary determines will improve preventive health
24 care for medicare beneficiaries, result in im-
25 proved chronic disease management, and man-

1 agement of complex, life-threatening, or high-
2 cost conditions and are consistent with the
3 goals described in subparagraphs (A), (B), and
4 (C) of paragraph (1).

5 (b) PROJECT SITES AND DURATION.—

6 (1) IN GENERAL.—Subject to subsection (e)(2),
7 the projects under this section shall be conducted—

8 (A) in a region or regions that are com-
9 parable (as determined by the Secretary) to the
10 region or regions that are designated as a high-
11 ly competitive region under subparagraph (A)
12 or (B) of section 1858(i)(1) of the Social Secu-
13 rity Act, as added by section 231 of this Act;
14 and

15 (B) during the years that a region or re-
16 gions are designated as such a highly competi-
17 tive region.

18 (2) RULE OF CONSTRUCTION.—For purposes of
19 paragraph (1), a comparable region does not nec-
20 essarily mean the identical region.

21 (c) WAIVER AUTHORITY.—The Secretary shall waive
22 compliance with the requirements of title XVIII of the So-
23 cial Security Act (42 U.S.C. 1395 et seq.) only to the ex-
24 tent and for such period as the Secretary determines is

1 necessary to provide for enhanced benefits or services con-
 2 sistent with the projects under this section.

3 (d) BIENNIAL GAO REPORTS.—Not later than Janu-
 4 ary 1, 2011, and biennially thereafter for as long as the
 5 projects under this section are being conducted, the Comp-
 6 troller General of the United States shall submit to the
 7 Secretary and Congress a report that evaluates the
 8 projects. Each report shall include—

9 (1) an evaluation of—

10 (A) the quality of care provided to bene-
 11 ficiaries receiving benefits or services under the
 12 projects;

13 (B) the satisfaction of beneficiaries receiv-
 14 ing benefits or services under the projects;

15 (C) the costs to the medicare program
 16 under the projects; and

17 (D) any improvements in the delivery of
 18 health care services under the projects; and

19 (2) recommendations for such legislation or ad-
 20 ministrative action as the Comptroller General deter-
 21 mines to be appropriate.

22 (e) FUNDING.—

23 (1) IN GENERAL.—Payments for the costs of
 24 carrying out the projects under this section shall be
 25 made from the Federal Hospital Insurance Trust

1 Fund under section 1817 of the Social Security Act
2 (42 U.S.C. 1395i) and the Federal Supplementary
3 Insurance Trust Fund under section 1841 of such
4 Act (42 U.S.C. 1395t), as determined appropriate
5 by the Secretary.

6 (2) LIMITATION.—The total amount expended
7 under the medicare fee-for-service program under
8 parts A and B of title XVIII of the Social Security
9 Act (including all amounts expended as a result of
10 the projects under this section) during the period or
11 year, as applicable, may not exceed—

12 (A) for the period beginning on January 1,
13 2009, and ending on September 30, 2013, an
14 amount equal to the total amount that would
15 have been expended under the medicare fee-for-
16 service program under parts A and B of title
17 XVIII of the Social Security Act during the pe-
18 riod if the projects had not been conducted plus
19 \$6,000,000,000; and

20 (B) for fiscal year 2014 and any subse-
21 quent fiscal year, an amount equal to the total
22 amount that would have been expended under
23 the medicare fee-for-service program under
24 parts A and B of such title during the year if
25 the projects had not been conducted.

1 (3) MONITORING AND REPORTS.—

2 (A) ONGOING MONITORING BY THE SEC-
 3 RETARY TO ENSURE FUNDING LIMITATION IS
 4 NOT VIOLATED.—The Secretary shall contin-
 5 ually monitor expenditures made under title
 6 XVIII of the Social Security Act by reason of
 7 the projects under this section to ensure that
 8 the limitations described in subparagraphs (A)
 9 and (B) of paragraph (2) are not violated.

10 (B) REPORTS.—Not later than April 1 of
 11 each year (beginning in 2010), the Secretary
 12 shall submit a report to Congress and the
 13 Comptroller General of the United States that
 14 includes—

15 (i) a detailed description of—

16 (I) the total amount expended
 17 under the medicare fee-for-service pro-
 18 gram under parts A and B of title
 19 XVIII of the Social Security Act (in-
 20 cluding all amounts expended as a re-
 21 sult of the projects under this section)
 22 during the previous year compared to
 23 the total amount that would have
 24 been expended under the original
 25 medicare fee-for-service program in

1 the year if the projects had not been

2 conducted;

3 (II) the projections of the total

4 amount expended under the medicare

5 fee-for-service program under parts A

6 and B of title XVIII of the Social Se-

7 curity Act (including all amounts ex-

8 pended as a result of the projects

9 under this section) during the year in

10 which the report is submitted com-

11 pared to the total amount that would

12 have been expended under the original

13 medicare fee-for-service program in

14 the year if the projects had not been

15 conducted;

16 (III) amounts remaining within

17 the funding limitation specified in

18 paragraph (2); and

19 (IV) how the Secretary will

20 change the scope, site, and duration

21 of the projects in subsequent years in

22 order to ensure that the limitations

23 described in subparagraphs (A) and

24 (B) of paragraph (2) are not violated;

25 and

(ii) a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that the descriptions under subclauses (I), (II), (III), and (IV) of clause (i) are reasonable, accurate, and based on generally accepted actuarial principles and methodologies.

(C) REPORT ON BUDGET NEUTRALITY FOR FISCAL YEARS AFTER 2013.—

(i) IN GENERAL.—If the Secretary intends to continue the projects under this section for fiscal year 2014 or any subsequent fiscal year, the Secretary shall submit a report to Congress indicating such intent no later than April 1 of the year prior to the year in which the fiscal year begins.

(ii) REQUIREMENTS.—A report submitted under clause (i) shall—

(I) specify the steps (if any) that the Secretary will take pursuant to paragraph (4) to ensure that the limitations described in paragraph (2)(B) will not be violated for the year; and

(II) contain a certification from the Chief Actuary of the Centers for Medicare and Medicaid Services that such steps will meet the requirements of paragraph (2) based on an analysis using generally accepted actuarial principles and methodologies.

(4) APPLICATION OF LIMITATION.—If the Secretary determines that the projects under this section will cause the limitations described in subparagraphs (A) and (B) of paragraph (2) to be violated, the Secretary shall take appropriate steps to reduce spending under the projects, including through reducing the scope, site, and duration of the projects.

(5) AUTHORITY.—Beginning in 2014, the Secretary shall make necessary spending adjustments (including pro rata reductions in payments to health care providers under the medicare program) to recoup amounts so that the limitations described in subparagraphs (A) and (B) of paragraph (2) are not violated.

1 **Subtitle E—National Bipartisan**
2 **Commission on Medicare Reform**

3 **SEC. 241. MEDICAREADVANTAGE GOAL; ESTABLISHMENT**
4 **OF COMMISSION.**

5 (a) **ENROLLMENT GOAL.**—It is the goal of this title
6 that, not later than January 1, 2010, at least 15 percent
7 of individuals entitled to, or enrolled for, benefits under
8 part A of title XVIII of the Social Security Act and en-
9 rolled under part B of such title should be enrolled in a
10 MedicareAdvantage plan, as determined by the Center for
11 Medicare Choices.

12 (b) **FAILURE TO ACHIEVE GOAL.**—If the goal de-
13 scribed in subsection (a) is not met by January 1, 2012,
14 as determined by the Center for Medicare Choices, there
15 shall be established a commission as described in section
16 2.

17 **SEC. 242. NATIONAL BIPARTISAN COMMISSION ON MEDI-**
18 **CARE REFORM.**

19 (a) **ESTABLISHMENT.**—Upon a determination under
20 section 241(b) that the enrollment goal has not been met,
21 there shall be established a commission to be known as
22 the National Bipartisan Commission on Medicare Reform
23 (in this section referred to as the “Commission”).

24 (b) **DUTIES OF THE COMMISSION.**—The Commission
25 shall—

1 (1) review and analyze the long-term financial
2 condition of the medicare program under title XVIII
3 of the Social Security Act (42 U.S.C. 1395 et seq.);

4 (2) identify problems that threaten the financial
5 integrity of the Federal Hospital Insurance Trust
6 Fund and the Federal Supplementary Medical In-
7 surance Trust Fund established under sections 1817
8 and 1841 of such Act (42 U.S.C. 1395i and 1395t),
9 including—

10 (A) the financial impact on the medicare
11 program of the significant increase in the num-
12 ber of medicare eligible individuals; and

13 (B) the ability of the Federal Government
14 to sustain the program into the future;

15 (3) analyze potential solutions to the problems
16 identified under paragraph (2) that will ensure both
17 the financial integrity of the medicare program and
18 the provision of appropriate benefits under such pro-
19 gram, including methods used by other nations to
20 respond to comparable demographic patterns in eli-
21 gibility for health care benefits for elderly and dis-
22 abled individuals and trends in employment-related
23 health care for retirees;

24 (4) make recommendations to restore the sol-
25 vency of the Federal Hospital Insurance Trust Fund

1 and the financial integrity of the Federal Supple-
 2 mentary Medical Insurance Trust Fund;

3 (5) make recommendations for establishing the
 4 appropriate financial structure of the medicare pro-
 5 gram as a whole;

6 (6) make recommendations for establishing the
 7 appropriate balance of benefits covered under, and
 8 beneficiary contributions to, the medicare program;

9 (7) make recommendations for the time periods
 10 during which the recommendations described in
 11 paragraphs (4), (5) and (6) should be implemented;

12 (8) make recommendations on the impact of
 13 chronic disease and disability trends on future costs
 14 and quality of services under the current benefit, fi-
 15 nancing, and delivery system structure of the medi-
 16 care program;

17 (9) make recommendations regarding a com-
 18 prehensive approach to preserve the medicare pro-
 19 gram, including ways to increase the effectiveness of
 20 the MedicareAdvantage program and to increase
 21 MedicareAdvantage enrollment rates; and

22 (10) review and analyze such other matters as
 23 the Commission determines appropriate.

24 (c) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 17 members, of whom—

(A) four shall be appointed by the President;

(B) six shall be appointed by the Majority Leader of the Senate, in consultation with the Minority Leader of the Senate, of whom not more than 4 shall be of the same political party;

(C) six shall be appointed by the Speaker of the House of Representatives, in consultation with the Minority Leader of the House of Representatives, of whom not more than 4 shall be of the same political party; and

(D) one, who shall serve as Chairperson of the Commission, shall be appointed jointly by the President, Majority Leader of the Senate, and the Speaker of the House of Representatives.

(2) DEADLINE FOR APPOINTMENT.—Members of the Commission shall be appointed by not later than October 1, 2012.

(3) TERMS OF APPOINTMENT.—The term of any member appointed under paragraph (1) shall be for the life of the Commission.

1 (4) MEETINGS.—The Commission shall meet at
 2 the call of the Chairperson or a majority of its mem-
 3 bers.

4 (5) QUORUM.—A quorum for purposes of con-
 5 ducting the business of the Commission shall consist
 6 of 8 members of the Commission, except that 4
 7 members may conduct a hearing under subsection
 8 (e).

9 (6) VACANCIES.—A vacancy in the membership
 10 of the Commission shall be filled, not later than 30
 11 days after the Commission is given notice of the va-
 12 cancy, in the same manner in which the original ap-
 13 pointment was made. Such a vacancy shall not affect
 14 the power of the remaining members to carry out
 15 the duties of the Commission.

16 (7) COMPENSATION.—Members of the Commis-
 17 sion shall receive no additional pay, allowances, or
 18 benefits by reason of their service on the Commis-
 19 sion.

20 (8) EXPENSES.—Each member of the Commis-
 21 sion shall receive travel expenses and per diem in
 22 lieu of subsistence in accordance with sections 5702
 23 and 5703 of title 5, United States Code.

24 (d) STAFF AND SUPPORT SERVICES.—

25 (1) EXECUTIVE DIRECTOR.—

(A) APPOINTMENT.—The Chairperson shall appoint an executive director of the Commission.

(B) COMPENSATION.—The executive director shall be paid the rate of basic pay for level V of the Executive Schedule under title 5, United States Code.

(2) STAFF.—With the approval of the Commission, the executive director may appoint such personnel as the executive director considers appropriate.

(3) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the Commission shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

(4) EXPERTS AND CONSULTANTS.—With the approval of the Commission, the executive director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

(5) PHYSICAL FACILITIES.—The Administrator of the General Services Administration shall locate

1 suitable office space for the operation of the Com-
 2 mission. The facilities shall serve as the head-
 3 quarters of the Commission and shall include all
 4 necessary equipment and incidentals required for the
 5 proper functioning of the Commission.

6 (e) POWERS OF COMMISSION.—

7 (1) HEARINGS AND OTHER ACTIVITIES.—The
 8 Commission may hold such hearings and undertake
 9 such other activities as the Commission determines
 10 to be necessary to carry out its duties under this
 11 section.

12 (2) STUDIES BY GAO.—Upon the request of the
 13 Commission, the Comptroller General shall conduct
 14 such studies or investigations as the Commission de-
 15 termines to be necessary to carry out its duties
 16 under this section.

17 (3) COST ESTIMATES BY CONGRESSIONAL
 18 BUDGET OFFICE AND OFFICE OF THE CHIEF ACTU-
 19 ARY OF THE CENTERS FOR MEDICARE & MED-
 20 ICAID.—

21 (A) IN GENERAL.—The Director of the
 22 Congressional Budget Office or the Chief Actu-
 23 ary of the Center for Medicare & Medicaid
 24 Services, or both, shall provide to the Commis-
 25 sion, upon the request of the Commission, such

1 cost estimates as the Commission determines to
2 be necessary to carry out its duties under this
3 section. ~~directly~~

4 (B) REIMBURSEMENTS.—The Commission
5 shall reimburse the Director of the Congres-
6 sional Budget Office for expenses relating to
7 the employment in the office of the Director of
8 such additional staff as may be necessary for
9 the Director to comply with requests by the
10 Commission under subparagraph (A).

11 (4) DETAIL OF FEDERAL EMPLOYEES.—Upon
12 the request of the Commission, the head of any Fed-
13 eral agency is authorized to detail, without reim-
14 bursement, any of the personnel of such agency to
15 the Commission to assist the Commission in car-
16 rying out its duties under this section. Any such de-
17 tail shall not interrupt or otherwise affect the civil
18 service status or privileges of the Federal employee.

19 (5) TECHNICAL ASSISTANCE.—Upon the re-
20 quest of the Commission, the head of a Federal
21 agency shall provide such technical assistance to the
22 Commission as the Commission determines to be
23 necessary to carry out its duties under this section.

24 (6) USE OF MAILS.—The Commission may use
25 the United States mails in the same manner and

1 under the same conditions as Federal agencies and
2 shall, for purposes of the frank, be considered a
3 commission of Congress as described in section 3215
4 of title 39, United States Code.

5 (7) OBTAINING INFORMATION.—The Commis-
6 sion may secure directly from any Federal agency
7 information necessary to enable it to carry out its
8 duties under this section, if the information may be
9 disclosed under section 552 of title 5, United States
10 Code. Upon request of the Chairperson of the Com-
11 mission, the head of each such agency shall furnish
12 such information to the Commission.

13 (8) ADMINISTRATIVE SUPPORT SERVICES.—
14 Upon the request of the Commission, the Adminis-
15 trator of General Services shall provide to the Com-
16 mission on a reimbursable basis such administrative
17 support services as the Commission may request.

18 (9) PRINTING.—For purposes of costs relating
19 to printing and binding, including the cost of per-
20 sonnel detailed from the Government Printing Of-
21 fice, the Commission shall be deemed to be a com-
22 mittee of Congress.

23 (f) REPORT.—Not later than April 1, 2014, the Com-
24 mission shall submit to the President and Congress a re-
25 port and an implementation bill that shall contain a de-

1 tailed statement of only those recommendations, findings,
2 and conclusions of the Commission that receive the ap-
3 proval of at least 11 members of the Commission.

4 (g) TERMINATION.—The Commission shall terminate
5 on the date that is 30 days after the date on which the
6 report and implementation bill is submitted under sub-
7 section (f).

8 **SEC. 243. CONGRESSIONAL CONSIDERATION OF REFORM**
9 **PROPOSALS.**

10 (a) DEFINITIONS.—In this section:

11 (1) IMPLEMENTATION BILL.—The term “imple-
12 mentation bill” means only a bill that is introduced
13 as provided under subsection (b), and contains the
14 proposed legislation included in the report submitted
15 to Congress under section 242(f), without modifica-
16 tion.

17 (2) CALENDAR DAY.—The term “calendar day”
18 means a calendar day other than 1 on which either
19 House is not in session because of an adjournment
20 of more than 3 days to a date certain.

21 (b) INTRODUCTION; REFERRAL; AND REPORT OR
22 DISCHARGE.—

23 (1) INTRODUCTION.—On the first calendar day
24 on which both Houses are in session immediately fol-
25 lowing the date on which the report is submitted to

1 Congress under section 242(f), a single implementa-
2 tion bill shall be introduced (by request)—

3 (A) in the Senate by the Majority Leader
4 of the Senate, for himself and the Minority
5 Leader of the Senate, or by Members of the
6 Senate designated by the Majority Leader and
7 Minority Leader of the Senate; and

8 (B) in the House of Representatives by the
9 Speaker of the House of Representatives, for
10 himself and the Minority Leader of the House
11 of Representatives, or by Members of the House
12 of Representatives designated by the Speaker
13 and Minority Leader of the House of Rep-
14 resentatives.

15 (2) REFERRAL.—The implementation bills in-
16 troduced under paragraph (1) shall be referred to
17 any appropriate committee of jurisdiction in the
18 Senate and any appropriate committee of jurisdic-
19 tion in the House of Representatives. A committee
20 to which an implementation bill is referred under
21 this paragraph may report such bill to the respective
22 House without amendment.

23 (3) REPORT OR DISCHARGE.—If a committee to
24 which an implementation bill is referred has not re-
25 ported such bill by the end of the 15th calendar day

1 after the date of the introduction of such bill, such
2 committee shall be immediately discharged from fur-
3 ther consideration of such bill, and upon being re-
4 ported or discharged from the committee, such bill
5 shall be placed on the appropriate calendar.

6 (c) FLOOR CONSIDERATION.—

7 (1) IN GENERAL.—When the committee to
8 which an implementation bill is referred has re-
9 ported, or has been discharged under subsection
10 (b)(3), it is at any time thereafter in order (even
11 though a previous motion to the same effect has
12 been disagreed to) for any Member of the respective
13 House to move to proceed to the consideration of the
14 implementation bill, and all points of order against
15 the implementation bill (and against consideration of
16 the implementation bill) are waived. The motion is
17 highly privileged in the House of Representatives
18 and is privileged in the Senate. The motion is not
19 subject to amendment, or to a motion to postpone,
20 or to a motion to proceed to the consideration of
21 other business. A motion to reconsider the vote by
22 which the motion is agreed to or disagreed to shall
23 not be in order. If a motion to proceed to the consid-
24 eration of the implementation bill is agreed to, the

1 Implementation bill shall remain the unfinished busi-
 2 ness of the respective House until disposed of.

3 (2) AMENDMENTS.—An implementation bill
 4 may not be amended in the Senate or the House of
 5 Representatives.

6 (3) DEBATE.—Debate on the implementation
 7 bill, and on all debatable motions and appeals in
 8 connection therewith, shall be limited to not more
 9 than 20 hours, which shall be divided equally be-
 10 tween those favoring and those opposing the resolu-
 11 tion. A motion further to limit debate is in order and
 12 not debatable. An amendment to, or a motion to
 13 postpone, or a motion to proceed to the consider-
 14 ation of other business, or a motion to recommit the
 15 implementation bill is not in order. A motion to re-
 16 consider the vote by which the implementation bill is
 17 agreed to or disagreed to is not in order.

18 (4) VOTE ON FINAL PASSAGE.—Immediately
 19 following the conclusion of the debate on an imple-
 20 mentation bill, and a single quorum call at the con-
 21 clusion of the debate if requested in accordance with
 22 the rules of the appropriate House, the vote on final
 23 passage of the implementation bill shall occur.

24 (5) RULINGS OF THE CHAIR ON PROCEDURE.—
 25 Appeals from the decisions of the Chair relating to

the application of the rules of the Senate or the House of Representatives, as the case may be, to the procedure relating to an implementation bill shall be decided without debate.

(d) COORDINATION WITH ACTION BY OTHER HOUSE.—If, before the passage by 1 House of an implementation bill of that House, that House receives from the other House an implementation bill, then the following procedures shall apply:

(1) NONREFERRAL.—The implementation bill of the other House shall not be referred to a committee.

(2) VOTE ON BILL OF OTHER HOUSE.—With respect to an implementation bill of the House receiving the implementation bill—

(A) the procedure in that House shall be the same as if no implementation bill had been received from the other House; but

(B) the vote on final passage shall be on the implementation bill of the other House.

(e) RULES OF SENATE AND HOUSE OF REPRESENTATIVES.—This section is enacted by Congress—

(1) as an exercise of the rulemaking power of the Senate and House of Representatives, respectively, and as such it is deemed a part of the rules

1 of each House, respectively, but applicable only with
 2 respect to the procedure to be followed in that
 3 House in the case of an implementation bill de-
 4 scribed in subsection (a), and it supersedes other
 5 rules only to the extent that it is inconsistent with
 6 such rules; and.

7 (2) with full recognition of the constitutional
 8 right of either House to change the rules (so far as
 9 relating to the procedure of that House) at any time,
 10 in the same manner, and to the same extent as in
 11 the case of any other rule of that House.

12 **SEC. 244. AUTHORIZATION OF APPROPRIATIONS.**

13 There are authorized to be appropriated such sums
 14 as may be necessary to carry out this subtitle for each
 15 of fiscal years 2012 through 2013.

16 **TITLE III—CENTER FOR** 17 **MEDICARE CHOICES**

18 **SEC. 301. ESTABLISHMENT OF THE CENTER FOR MEDICARE** 19 **CHOICES.**

20 (a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et
 21 seq.), as amended by section 111, is amended by inserting
 22 after 1806 the following new section:

23 “ESTABLISHMENT OF THE CENTER FOR MEDICARE
 24 CHOICES

25 “SEC. 1808. (a) ESTABLISHMENT.—By not later
 26 than March 1, 2004, the Secretary shall establish within

1 the Department of Health and Human Services the Center
 2 for Medicare Choices, which shall be separate from the
 3 Centers for Medicare & Medicaid Services.

4 “(b) ADMINISTRATOR AND DEPUTY ADMINIS-
 5 TRATOR.—

6 “(1) ADMINISTRATOR.—

7 “(A) IN GENERAL.—The Center for Medi-
 8 care Choices shall be headed by an Adminis-
 9 trator (in this section referred to as the ‘Ad-
 10 ministrator’) who shall be appointed by the
 11 President, by and with the advice and consent
 12 of the Senate. The Administrator shall report
 13 directly to the Secretary.

14 “(B) COMPENSATION.—The Administrator
 15 shall be paid at the rate of basic pay payable
 16 for level III of the Executive Schedule under
 17 section 5314 of title 5, United States Code.

18 “(C) TERM OF OFFICE.—The Adminis-
 19 trator shall be appointed for a term of 5 years.
 20 In any case in which a successor does not take
 21 office at the end of an Administrator’s term of
 22 office, that Administrator may continue in of-
 23 fice until the entry upon office of such a suc-
 24 cessor. An Administrator appointed to a term of
 25 office after the commencement of such term

1 may serve under such appointment only for the
2 remainder of such term.

3 “(D) GENERAL AUTHORITY.—The Admin-
4 istrator shall be responsible for the exercise of
5 all powers and the discharge of all duties of the
6 Center for Medicare Choices, and shall have au-
7 thority and control over all personnel and ac-
8 tivities thereof.

9 “(E) RULEMAKING AUTHORITY.—The Ad-
10 ministrator may prescribe such rules and regu-
11 lations as the Administrator determines nec-
12 essary or appropriate to carry out the functions
13 of the Center for Medicare Choices. The regula-
14 tions prescribed by the Administrator shall be
15 subject to the rulemaking procedures estab-
16 lished under section 553 of title 5, United
17 States Code.

18 “(F) AUTHORITY TO ESTABLISH ORGANI-
19 ZATIONAL UNITS.—The Administrator may es-
20 tablish, alter, consolidate, or discontinue such
21 organizational units or components within the
22 Center for Medicare Choices as the Adminis-
23 trator considers necessary or appropriate, ex-
24 cept that this subparagraph shall not apply

1 with respect to any unit, component, or provi-
 2 sion provided for by this section. "

3 "(G) AUTHORITY TO DELEGATE.—The Ad-
 4 ministrator may assign duties, and delegate, or
 5 authorize successive redelegations of, authority
 6 to act and to render decisions, to such officers
 7 and employees of the Center for Medicare
 8 Choices as the Administrator may find nec-
 9 essary. Within the limitations of such delega-
 10 tions, redelegations, or assignments, all official
 11 acts and decisions of such officers and employ-
 12 ees shall have the same force and effect as
 13 though performed or rendered by the Adminis-
 14 trator.

15 "(2) DEPUTY ADMINISTRATOR.—

16 "(A) IN GENERAL.—There shall be a Dep-
 17 uty Administrator of the Center for Medicare
 18 Choices who shall be appointed by the Adminis-
 19 trator. *10/10/2010 10:10:10 AM*

20 "(B) COMPENSATION.—The Deputy Ad-
 21 ministrator shall be paid at the rate of basic
 22 pay payable for level IV of the Executive Sched-
 23 ule under section 5315 of title 5, United States
 24 Code. *10/10/2010 10:10:10 AM*

1 “(C) TERM OF OFFICE.—The Deputy Ad-
2 ministrators shall be appointed for a term of 5
3 years. In any case in which a successor does not
4 take office at the end of a Deputy Administra-
5 tor’s term of office, such Deputy Administrator
6 may continue in office until the entry upon of-
7 fice of such a successor. A Deputy Adminis-
8 trator appointed to a term of office after the
9 commencement of such term may serve under
10 such appointment only for the remainder of
11 such term.

12 “(D) DUTIES.—The Deputy Administrator
13 shall perform such duties and exercise such
14 powers as the Administrator shall from time to
15 time assign or delegate. The Deputy Adminis-
16 trator shall be the Acting Administrator of the
17 Center for Medicare Choices during the absence
18 or disability of the Administrator and, unless
19 the President designates another officer of the
20 Government as Acting Administrator, in the
21 event of a vacancy in the office of the Adminis-
22 trator.

23 “(3) SECRETARIAL COORDINATION OF PROGRAM
24 ADMINISTRATION.—The Secretary shall ensure ap-
25 propriate coordination between the Administrator

1 and the Administrator of the Centers for Medicare
 2 & Medicaid Services in carrying out the programs
 3 under this title.

4 “(c) DUTIES; ADMINISTRATIVE PROVISIONS.—

5 “(1) DUTIES.—

6 “(A) GENERAL DUTIES.—The Adminis-
 7 trator shall carry out parts C and D, includ-
 8 ing—

9 “(i) negotiating, entering into, and en-
 10 forcing, contracts with plans for the offer-
 11 ing of Medicare Advantage plans under
 12 part C, including the offering of qualified
 13 prescription drug coverage under such
 14 plans; and

15 “(ii) negotiating, entering into, and
 16 enforcing, contracts with eligible entities
 17 for the offering of Medicare Prescription
 18 Drug plans under part D.

19 “(B) OTHER DUTIES.—The Administrator
 20 shall carry out any duty provided for under
 21 part C or D, including duties relating to—

22 “(i) reasonable cost contracts with eli-
 23 gible organizations under section 1876(h);
 24 and

1 “(ii) demonstration projects carried
 2 out in part or in whole under such parts,
 3 including the demonstration project carried
 4 out through a MedicareAdvantage (for-
 5 merly Medicare+Choice) project that dem-
 6 onstrates the application of capitation pay-
 7 ment rates for frail elderly medicare bene-
 8 ficiaries through the use of an interdiscipli-
 9 nary team and through the provision of
 10 primary care services to such beneficiaries
 11 by means of such a team at the nursing fa-
 12 cility involved.

13 “(C) NONINTERFERENCE.—In order to
 14 promote competition under parts C and D, the
 15 Administrator, in carrying out the duties re-
 16 quired under this section, may not, to the ex-
 17 tent possible, interfere in any way with negotia-
 18 tions between eligible entities,
 19 MedicareAdvantage organizations, hospitals,
 20 physicians, other entities or individuals fur-
 21 nishing items and services under this title (in-
 22 cluding contractors for such items and serv-
 23 ices), and drug manufacturers, wholesalers, or
 24 other suppliers of covered drugs

“(D) ANNUAL REPORTS.—Not later than March 31 of each year, the Administrator shall submit to Congress and the President a report on the administration of the voluntary prescription drug delivery program under this part during the previous fiscal year.

“(2) MANAGEMENT STAFF.—

“(A) IN GENERAL.—The Administrator, with the approval of the Secretary, may employ, such management staff as determined appropriate. Any such manager shall be required to have demonstrated, by their education and experience (either in the public or private sector), superior expertise in the following areas:

“(i) The review, negotiation, and administration of health care contracts.

“(ii) The design of health care benefit plans.

“(iii) Actuarial sciences.

“(iv) Compliance with health plan contracts.

“(v) Consumer education and decision making.

“(B) COMPENSATION.—

1 “(i) IN GENERAL.—Subject to clause
2 (ii), the Administrator shall establish the
3 rate of pay for an individual employed
4 under subparagraph (A).

5 “(ii) MAXIMUM RATE.—In no case
6 may the rate of compensation determined
7 under clause (i) exceed the highest rate of
8 basic pay for the Senior Executive Service
9 under section 5382(b) of title 5, United
10 States Code.

11 “(3) REDELEGATION OF CERTAIN FUNCTIONS
12 OF THE CENTERS FOR MEDICARE & MEDICAID SERV-
13 ICES.—

14 “(A) IN GENERAL.—The Secretary, the
15 Administrator of the Center for Medicare
16 Choices, and the Administrator of the Centers
17 for Medicare & Medicaid Services shall establish
18 an appropriate transition of responsibility in
19 order to redelegate the administration of part C
20 from the Secretary and the Administrator of
21 the Centers for Medicare & Medicaid Services
22 to the Administrator of the Center for Medicare
23 Choices as is appropriate to carry out the pur-
24 poses of this section.

1 “(B) TRANSFER OF DATA AND INFORMA-
 2 TION.—The Secretary shall ensure that the Ad-
 3 ministrator of the Centers for Medicare & Med-
 4 icaid Services transfers to the Administrator
 5 such information and data in the possession of
 6 the Administrator of the Centers for Medicare
 7 & Medicaid Services as the Administrator re-
 8 quires to carry out the duties described in para-
 9 graph (1).

10 “(C) CONSTRUCTION.—Insofar as a re-
 11 sponsibility of the Secretary or the Adminis-
 12 trator of the Centers for Medicare & Medicaid
 13 Services is redelegated to the Administrator
 14 under this section, any reference to the Sec-
 15 retary or the Administrator of the Centers for
 16 Medicare & Medicaid Services in this title or
 17 title XI with respect to such responsibility is
 18 deemed to be a reference to the Administrator.

19 “(d) OFFICE OF BENEFICIARY ASSISTANCE.—

20 “(1) ESTABLISHMENT.—The Secretary shall es-
 21 tablish within the Center for Medicare Choices an
 22 Office of Beneficiary Assistance to carry out func-
 23 tions relating to medicare beneficiaries under this
 24 title, including making determinations of eligibility
 25 of individuals for benefits under this title, providing

1 for enrollment of medicare beneficiaries under this
 2 title, and the functions described in paragraph (2).
 3 The Office shall be a separate operating division
 4 within the Center for Medicare Choices.

5 *Section 1882* “(2) DISSEMINATION OF INFORMATION ON
 6 BENEFITS AND APPEALS RIGHTS.—

7 “(A) DISSEMINATION OF BENEFITS INFOR-
 8 MATION.—The Office of Beneficiary Assistance
 9 shall disseminate to medicare beneficiaries, by
 10 mail, by posting on the Internet site of the Cen-
 11 ter for Medicare Choices, and through the toll-
 12 free telephone number provided for under sec-
 13 tion 1804(b), information with respect to the
 14 following:

15 “(i) Benefits, and limitations on pay-
 16 ment (including cost-sharing, stop-loss pro-
 17 visions, and formulary restrictions) under
 18 parts C and D.

19 “(ii) Benefits, and limitations on pay-
 20 ment under parts A, and B, including in-
 21 formation on medicare supplemental poli-
 22 cies under section 1882.

23 “(iii) Other areas determined to be
 24 appropriate by the Administrator.

1 Such information shall be presented in a man-
2 ner so that medicare beneficiaries may compare
3 benefits under parts A, B, and D, and medicare
4 supplemental policies with benefits under
5 MedicareAdvantage plans under part C.

6 “(B) DISSEMINATION OF APPEALS RIGHTS
7 INFORMATION.—The Office of Beneficiary As-
8 sistance shall disseminate to medicare bene-
9 ficiaries in the manner provided under subpara-
10 graph (A) a description of procedural rights (in-
11 cluding grievance and appeals procedures) of
12 beneficiaries under the original medicare fee-
13 for-service program under parts A and B, the
14 MedicareAdvantage program under part C, and
15 the voluntary prescription drug delivery pro-
16 gram under part D.

17 “(3) MEDICARE OMBUDSMAN.—

18 “(A) IN GENERAL.—Within the Office of
19 Beneficiary Assistance, there shall be a Medi-
20 care Ombudsman, appointed by the Secretary
21 from among individuals with expertise and ex-
22 perience in the fields of health care and advo-
23 cacy, to carry out the duties described in sub-
24 paragraph (B).

1 “(B) DUTIES.—The Medicare Ombudsman
2 shall—

3 “(i) receive complaints, grievances,
4 and requests for information submitted by
5 a medicare beneficiary, with respect to any
6 aspect of the medicare program;

7 “(ii) provide assistance with respect to
8 complaints, grievances, and requests re-
9 ferred to in clause (i), including—

10 “(I) assistance in collecting rel-
11 evant information for such bene-
12 ficiaries, to seek an appeal of a deci-
13 sion or determination made by a fiscal
14 intermediary, carrier,
15 MedicareAdvantage organization, an
16 eligible entity under part D, or the
17 Secretary; and

18 “(II) assistance to such bene-
19 ficiaries with any problems arising
20 from disenrollment from a
21 MedicareAdvantage plan under part C
22 or a prescription drug plan under part
23 D; and

24 “(iii) submit annual reports to Con-
25 gress, the Secretary, and the Medicare

Competitive Policy Advisory Board describing the activities of the Office, and including such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

“(C) COORDINATION WITH STATE OMBUDSMAN PROGRAMS AND CONSUMER ORGANIZATIONS.—The Medicare Ombudsman shall, to the extent appropriate, coordinate with State medical Ombudsman programs, and with State- and community-based consumer organizations, to—

“(i) provide information about the medicare program; and

“(ii) conduct outreach to educate medicare beneficiaries with respect to manners in which problems under the medicare program may be resolved or avoided.

“(e) MEDICARE COMPETITIVE POLICY ADVISORY BOARD.—

“(1) ESTABLISHMENT.—There is established within the Center for Medicare Choices the Medicare Competitive Policy Advisory Board (in this section referred to as the ‘Board’). The Board shall advise, consult with, and make recommendations to the Ad-

1 administrator with respect to the administration of
2 parts C and D, including the review of payment poli-
3 cies under such parts.

4 “(2) REPORTS.—

5 “(A) IN GENERAL.—With respect to mat-
6 ters of the administration of parts C and D, the
7 Board shall submit to Congress and to the Ad-
8 ministrator such reports as the Board deter-
9 mines appropriate. Each such report may con-
10 tain such recommendations as the Board deter-
11 mines appropriate for legislative or administra-
12 tive changes to improve the administration of
13 such parts, including the stability and solvency
14 of the programs under such parts and the top-
15 ics described in subparagraph (B). Each such
16 report shall be published in the Federal Reg-
17 ister.

18 “(B) TOPICS DESCRIBED.—Reports re-
19 quired under subparagraph (A) may include the
20 following topics:

21 “(i) FOSTERING COMPETITION.—Rec-
22 ommendations or proposals to increase
23 competition under parts C and D for serv-
24 ices furnished to medicare beneficiaries.

1 “(ii) EDUCATION AND ENROLL-
2 MENT.—Recommendations for the im-
3 provement of efforts to provide medicare
4 beneficiaries information and education on
5 the program under this title, and specifi-
6 cally parts C and D, and the program for
7 enrollment under the title.

8 “(iii) QUALITY.—Recommendations
9 on ways to improve the quality of benefits
10 provided under plans under parts C and D.

11 “(iv) DISEASE MANAGEMENT PRO-
12 GRAMS.—Recommendations on the incor-
13 poration of disease management programs
14 under parts C and D.

15 “(v) RURAL ACCESS.—Recommendations
16 to improve competition and access to
17 plans under parts C and D in rural areas.

18 “(C) MAINTAINING INDEPENDENCE OF
19 BOARD.—The Board shall directly submit to
20 Congress reports required under subparagraph
21 (A). No officer or agency of the United States
22 may require the Board to submit to any officer
23 or agency of the United States for approval,
24 comments, or review, prior to the submission to
25 Congress of such reports.

1 “(3) DUTY OF ADMINISTRATOR.—With respect
2 to any report submitted by the Board under para-
3 graph (2)(A), not later than 90 days after the report
4 is submitted, the Administrator shall submit to Con-
5 gress and the President an analysis of recommenda-
6 tions made by the Board in such report. Each such
7 analysis shall be published in the Federal Register.

8 “(4) MEMBERSHIP.—

9 “(A) APPOINTMENT.—Subject to the suc-
10 ceeding provisions of this paragraph, the Board
11 shall consist of 7 members to be appointed as
12 follows:

13 “(i) Three members shall be ap-
14 pointed by the President.

15 “(ii) Two members shall be appointed
16 by the Speaker of the House of Represent-
17 atives, with the advice of the chairman and
18 the ranking minority member of the Com-
19 mittees on Ways and Means and on En-
20 ergy and Commerce of the House of Rep-
21 resentatives.

22 “(iii) Two members shall be appointed
23 by the President pro tempore of the Senate
24 with the advice of the chairman and the

1 ranking minority member of the Com-
2 mittee on Finance of the Senate.

3 “(B) QUALIFICATIONS.—The members
4 shall be chosen on the basis of their integrity,
5 impartiality, and good judgment, and shall be
6 individuals who are, by reason of their edu-
7 cation and experience in health care benefits
8 management, exceptionally qualified to perform
9 the duties of members of the Board.

10 “(C) PROHIBITION ON INCLUSION OF FED-
11 ERAL EMPLOYEES.—No officer or employee of
12 the United States may serve as a member of
13 the Board.

14 “(5) COMPENSATION.—Members of the Board
15 shall receive, for each day (including travel time)
16 they are engaged in the performance of the functions
17 of the Board, compensation at rates not to exceed
18 the daily equivalent to the annual rate in effect for
19 level IV of the Executive Schedule under section
20 5315 of title 5, United States Code.

21 “(6) TERMS OF OFFICE.—

22 “(A) IN GENERAL.—The term of office of
23 members of the Board shall be 3 years.

1 “(B) TERMS OF INITIAL APPOINTEES.—As
2 designated by the President at the time of ap-
3 pointment, of the members first appointed—

4 “(i) one shall be appointed for a term
5 of 1 year;

6 “(ii) three shall be appointed for
7 terms of 2 years; and

8 “(iii) three shall be appointed for
9 terms of 3 years.

10 “(C) REAPPOINTMENTS.—Any person ap-
11 pointed as a member of the Board may not
12 serve for more than 8 years.

13 “(D) VACANCY.—Any member appointed
14 to fill a vacancy occurring before the expiration
15 of the term for which the member's predecessor
16 was appointed shall be appointed only for the
17 remainder of that term. A member may serve
18 after the expiration of that member's term until
19 a successor has taken office. A vacancy in the
20 Board shall be filled in the manner in which the
21 original appointment was made.

22 “(7) CHAIR.—The Chair of the Board shall be
23 elected by the members. The term of office of the
24 Chair shall be 3 years.

“(8) MEETINGS.—The Board shall meet at the call of the Chair, but in no event less than 3 times during each fiscal year.

“(9) DIRECTOR AND STAFF.—

“(A) APPOINTMENT OF DIRECTOR.—The Board shall have a Director who shall be appointed by the Chair.

“(B) IN GENERAL.—With the approval of the Board, the Director may appoint such additional personnel as the Director considers appropriate.

“(C) ASSISTANCE FROM THE ADMINISTRATOR.—The Administrator shall make available to the Board such information and other assistance as it may require to carry out its functions.

“(10) CONTRACT AUTHORITY.—The Board may contract with and compensate government and private agencies or persons to carry out its duties under this subsection, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

“(f) FUNDING.—There is authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Prescription

1 Drug Account), such sums as are necessary to carry out
2 this section.”.

3 (b) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-
4 MEDICARE).—Section 1804(b) (42 U.S.C. 1395b-2(b))
5 is amended by adding at the end the following: “By not
6 later than 1 year after the date of the enactment of the
7 Prescription Drug and Medicare Improvement Act of
8 2003, the Secretary shall provide, through the toll-free
9 number 1-800-MEDICARE, for a means by which indi-
10 viduals seeking information about, or assistance with, such
11 programs who phone such toll-free number are transferred
12 (without charge) to appropriate entities for the provision
13 of such information or assistance. Such toll-free number
14 shall be the toll-free number listed for general information
15 and assistance in the annual notice under subsection (a)
16 instead of the listing of numbers of individual contrac-
17 tors.”.

18 **SEC. 302. MISCELLANEOUS ADMINISTRATIVE PROVISIONS.**

19 (a) ADMINISTRATOR AS MEMBER AND CO-SEC-
20 RETARY OF THE BOARD OF TRUSTEES OF THE MEDICARE
21 TRUST FUNDS.—The fifth sentence of sections 1817(b)
22 and 1841(b) (42 U.S.C. 1395i(b), 1395t(b)) are each
23 amended by striking “shall serve as the Secretary” and
24 inserting “and the Administrator of the Center for Medi-
25 care Choices shall serve as the Co-Secretaries”.

1 (b) INCREASE IN GRADE TO EXECUTIVE LEVEL III
 2 FOR THE ADMINISTRATOR OF THE CENTERS FOR MEDI-
 3 CARE & MEDICAID SERVICES.—

4 (1) IN GENERAL.—Section 5314 of title 5,
 5 United States Code, is amended by adding at the
 6 end the following:

7 “Administrator of the Centers for Medicare &
 8 Medicaid Services.”.

9 (2) CONFORMING AMENDMENT.—Section 5315
 10 of such title is amended by striking “Administrator
 11 of the Health Care Financing Administration.”.

12 (3) EFFECTIVE DATE.—The amendments made
 13 by this subsection take effect on March 1, 2004.

14 **TITLE IV—MEDICARE FEE-FOR-**
 15 **SERVICE IMPROVEMENTS**
 16 **Subtitle A—Provisions Relating to**
 17 **Part A**

18 **SEC. 401. EQUALIZING URBAN AND RURAL STANDARDIZED**
 19 **PAYMENT AMOUNTS UNDER THE MEDICARE**
 20 **INPATIENT HOSPITAL PROSPECTIVE PAY-**
 21 **MENT SYSTEM.**

22 (a) IN GENERAL.—Section 1886(d)(3)(A)(iv) (42
 23 U.S.C. 1395ww(d)(3)(A)(iv)) is amended—

1 (1) by striking “(iv) For discharges” and in-
 2 serting “(iv)(I) Subject to subclause (II), for dis-
 3 charges”; and
 4 (2) by adding at the end the following new sub-
 5 clause:

6 “(II) For discharges occurring in a fiscal year
 7 (beginning with fiscal year 2004), the Secretary
 8 shall compute a standardized amount for hospitals
 9 located in any area within the United States and
 10 within each region equal to the standardized amount
 11 computed for the previous fiscal year under this sub-
 12 paragraph for hospitals located in a large urban area
 13 (or, beginning with fiscal year 2005, for applicable
 14 for all hospitals in the previous fiscal year) increased
 15 by the applicable percentage increase under sub-
 16 section (b)(3)(B)(i) for the fiscal year involved.”.

17 (b) APPLICATION TO SUBSECTION (D) PUERTO RICO
 18 HOSPITALS.—Section 1886(d)(9) (42 U.S.C.
 19 1395ww(d)(9)) is amended—

20 (1) in subparagraph (A)—

21 (A) in clause (i), by striking “and” after
 22 the comma at the end;

23 (B) in clause (ii)—

(i) in the matter preceding subclause (I), by inserting “and before October 1, 2003” after “October 1, 1997”; and

(ii) in the matter following clause (III), by striking the period at the end and inserting “, and”; and

(iii) by adding at the end the following new clause:

“(iii) for discharges in a fiscal year beginning on or after October 1, 2003, 50 percent of the national standardized rate (determined under paragraph (3)(D)(iii)) for hospitals located in any area.”;

(2) in subparagraph (C)—

(A) in clause (i)—

(i) by striking “(i) The Secretary” and inserting “(i)(I) For discharges in a fiscal year after fiscal year 1988 and before fiscal year 2004, the Secretary; and

(ii) by adding at the end the fol-

lowing:

“(II) For discharges in fiscal year 2004, the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year

2003 for hospitals in an urban area, increased by the applicable percentage increase under subsection (b)(3)(B) for fiscal year 2004.

“(III) For discharges in a fiscal year after fiscal year 2004, the Secretary shall compute an average standardized amount for hospitals located in any are of Puerto Rico that is equal to the average standardized amount computed under subclause (II) or this subclause for the previous fiscal year, increased by the applicable percentage increase under subsection (b)(3)(B), adjusted to reflect the most recent case mix data.”;

(B) in clause (ii), by inserting “(or for fiscal year 2004 and thereafter, the standardized amount)” after “each of the average standardized amounts”; and

(C) in clause (iii)(I), by striking “for hospitals located in an urban or rural area, respectively”.

(c) CONFORMING AMENDMENTS.—

(1) COMPUTING DRG-SPECIFIC RATES.—Section 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

(A) in the heading, by striking “IN DIFFERENT AREAS”;

(B) in the matter preceding clause (i), by striking “, each of”;

(C) in clause (i)—

(i) in the matter preceding subclause

(I), by inserting “for fiscal years before fiscal year 2004,” before “for hospitals”; and

(ii) in subclause (II), by striking “and” after the semicolon at the end;

(D) in clause (ii)—

(i) in the matter preceding subclause

(I), by inserting “for fiscal years before fiscal year 2004,” before “for hospitals”; and

(ii) in subclause (II), by striking the period at the end and inserting “; and”;

and

(E) by adding at the end the following new clause:

“(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of—

“(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

1 “(II) the weighting factor (determined
2 under paragraph (4)(B)) for that diag-
3 nosis-related group.”.

4 (2) TECHNICAL CONFORMING SUNSET.—Section
5 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

6 (A) in the matter preceding subparagraph
7 (A), by inserting “, for fiscal years before fiscal
8 year 1997,” before “a regional adjusted DRG
9 prospective payment rate”; and

10 (B) in subparagraph (D), in the matter
11 preceding clause (i), by inserting “, for fiscal
12 years before fiscal year 1997,” before “a re-
13 gional DRG prospective payment rate for each
14 region,”.

15 **SEC. 402. ADJUSTMENT TO THE MEDICARE INPATIENT HOS-**
16 **PITAL PPS WAGE INDEX TO REVISE THE**
17 **LABOR-RELATED SHARE OF SUCH INDEX.**

18 (a) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C.
19 1395ww(d)(3)(E)) is amended—

20 (1) by striking “WAGE LEVELS.—The Sec-
21 retary” and inserting “WAGE LEVELS.—

22 “(i) IN GENERAL.—Except as provided in
23 clause (ii), the Secretary”; and

24 (2) by adding at the end the following new
25 clause:

“(ii) ALTERNATIVE PROPORTION TO BE
ADJUSTED BEGINNING IN FISCAL YEAR 2005.—

“(I) IN GENERAL.—Except as pro-
vided in subclause (II), for discharges oc-
curring on or after October 1, 2004, the
Secretary shall substitute ‘62 percent’ for
the proportion described in the first sen-
tence of clause (i).

“(II) HOLD HARMLESS FOR CERTAIN
HOSPITALS.—If the application of sub-
clause (I) would result in lower payments
to a hospital than would otherwise be
made, then this subparagraph shall be ap-
plied as if this clause had not been en-
acted.”.

(b) WAIVING BUDGET NEUTRALITY.—Section
1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended
by subsection (a), is amended by adding at the end of
clause (i) the following new sentence: “The Secretary shall
apply the previous sentence for any period as if the
amendments made by section 402(a) of the Prescription
Drug and Medicare Improvement Act of 2003 had not
been enacted.”.

1 **SEC. 403. MEDICARE INPATIENT HOSPITAL PAYMENT AD-**
 2 **JUSTMENT FOR LOW-VOLUME HOSPITALS.**

3 Section 1886(d) (42 U.S.C. 1395ww(d)) is amended
 4 by adding at the end the following new paragraph:

5 “(12) PAYMENT ADJUSTMENT FOR LOW-VOL-
 6 UME HOSPITALS.—

7 “(A) PAYMENT ADJUSTMENT.—

8 “(i) IN GENERAL.—Notwithstanding
 9 any other provision of this section, for each
 10 cost reporting period (beginning with the
 11 cost reporting period that begins in fiscal
 12 year 2005), the Secretary shall provide for
 13 an additional payment amount to each low-
 14 volume hospital (as defined in clause (iii))
 15 for discharges occurring during that cost
 16 reporting period which is equal to the ap-
 17 plicable percentage increase (determined
 18 under clause (ii)) in the amount paid to
 19 such hospital under this section for such
 20 discharges.

21 “(ii) APPLICABLE PERCENTAGE IN-
 22 CREASE.—The Secretary shall determine a
 23 percentage increase applicable under this
 24 paragraph that ensures that—

25 “(I) no percentage increase in
 26 payments under this paragraph ex-

ceeds 25 percent of the amount of
 payment that would (but for this
 paragraph) otherwise be made to a
 low-volume hospital under this section
 for each discharge;

“(II) low-volume hospitals that
 have the lowest number of discharges
 during a cost reporting period receive
 the highest percentage increases in
 payments due to the application of
 this paragraph; and

“(III) the percentage increase in
 payments to any low-volume hospital
 due to the application of this para-
 graph is reduced as the number of
 discharges per cost reporting period
 increases.

“(iii) LOW-VOLUME HOSPITAL DE-
 FINED.—For purposes of this paragraph,
 the term ‘low-volume hospital’ means, for a
 cost reporting period, a subsection (d) hos-
 pital (as defined in paragraph (1)(B))
 other than a critical access hospital (as de-
 fined in section 1861(mm)(1)) that—

1 “(I) the Secretary determines
 2 had an average of less than 2,000 dis-
 3 charges (determined with respect to
 4 all patients and not just individuals
 5 receiving benefits under this title)
 6 during the 3 most recent cost report-
 7 ing periods for which data are avail-
 8 able that precede the cost reporting
 9 period to which this paragraph ap-
 10 plies; and

11 “(II) is located at least 15 miles
 12 from a like hospital (or is deemed by
 13 the Secretary to be so located by rea-
 14 son of such factors as the Secretary
 15 determines appropriate, including the
 16 time required for an individual to
 17 travel to the nearest alternative source
 18 of appropriate inpatient care (after
 19 taking into account the location of
 20 such alternative source of inpatient
 21 care and any weather or travel condi-
 22 tions that may affect such travel
 23 time).

24 “(B) PROHIBITING CERTAIN REDUC-
 25 TIONS.—Notwithstanding subsection (e), the

Secretary shall not reduce the payment amounts under this section to offset the increase in payments resulting from the application of subparagraph (A).”.

SEC. 404. FAIRNESS IN THE MEDICARE DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT FOR RURAL HOSPITALS.

(a) EQUALIZING DSH PAYMENT AMOUNTS.—

(1) IN GENERAL.—Section 1886(d)(5)(F)(vii) (42 U.S.C. 1395ww(d)(5)(F)(vii)) is amended by inserting “, and, after October 1, 2004, for any other hospital described in clause (iv),” after “clause (iv)(I)” in the matter preceding subclause (I).

(2) CONFORMING AMENDMENTS.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

clause (A) in clause (iv)—

clause (i) in subclause (II)—

clause (I) by inserting “and before October 1, 2004,” after “April 1,

2001,”; and

clause (II) by inserting “or, for dis-

charges occurring on or after October

1, 2004, is equal to the percent deter-

mined in accordance with the applica-

1 ble formula described in clause (vii)”
 2 after “clause (xiii)”;

3 (ii) in subclause (III)—

4 (I) by inserting “and before Oc-
 5 tober 1, 2004,” after “April 1,
 6 2001,”; and

7 (II) by inserting “or, for dis-
 8 charges occurring on or after October
 9 1, 2004, is equal to the percent deter-
 10 mined in accordance with the applica-
 11 ble formula described in clause (vii)”
 12 after “clause (xii)”;

13 (iii) in subclause (IV)—

14 (I) by inserting “and before Oc-
 15 tober 1, 2004,” after “April 1,
 16 2001,”; and

17 (II) by inserting “or, for dis-
 18 charges occurring on or after October
 19 1, 2004, is equal to the percent deter-
 20 mined in accordance with the applica-
 21 ble formula described in clause (vii)”

22 after “clause (x) or (xi)”;

23 (iv) in subclause (V)—

(I) by inserting “and before October 1, 2004,” after “April 1, 2001,”; and

(II) by inserting “or, for discharges occurring on or after October 1, 2004, is equal to the percent determined in accordance with the applicable formula described in clause (vii)” after “clause (xi)”;

(v) in subclause (VI)—

(I) by inserting “and before October 1, 2004,” after “April 1, 2001,”; and

(II) by inserting “or, for discharges occurring on or after October 1, 2004, is equal to the percent determined in accordance with the applicable formula described in clause (vii)” after “clause (x)”;

(B) in clause (viii), by striking “The formula” and inserting “For discharges occurring before October 1, 2004, the formula”; and

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking “For purposes” and inserting

1 “With respect to discharges occurring before
2 October 1, 2004, for purposes”.

3 (b) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to discharges occurring on or after
5 October 1, 2004.

6 **SEC. 404A. MEDPAC STUDY AND REPORT REGARDING MEDI-**
7 **CARE DISPROPORTIONATE SHARE HOSPITAL**
8 **(DSH) ADJUSTMENT PAYMENTS.**

9 (a) STUDY.—The Medicare Payment Advisory Com-
10 mission established under section 1805 of the Social Secu-
11 rity Act (42 U.S.C. 1395b–6) (in this section referred to
12 as “MedPAC”) shall conduct a study to determine, with
13 respect to additional payment amounts paid to subsection
14 (d) hospitals under section 1886(d)(5)(F) of the Social Se-
15 curity Act (42 U.S.C. 1395ww(d)(5)(F))—

16 (1) whether such payments should be made in
17 the same manner as payments are made with respect
18 to graduate medical education under title XVIII and
19 with respect to hospitals that serve a dispropor-
20 tionate share of low-income patients under the med-
21 icaid program; and

22 (2) whether to add costs attributable to uncom-
23 pensated care to the formula for determining such
24 payment amounts.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, MedPAC shall submit a report to Congress on the study conducted under subsection (a), together with such recommendations for legislation as MedPAC determines are appropriate.

SEC. 405. CRITICAL ACCESS HOSPITAL (CAH) IMPROVEMENTS.

(a) PERMITTING CAHS TO ALLOCATE SWING BEDS AND ACUTE CARE INPATIENT BEDS SUBJECT TO A TOTAL LIMIT OF 25 BEDS.—

(1) IN GENERAL.—Section 1820(c)(2)(B)(iii) (42 U.S.C. 1395i-4(c)(2)(B)(iii)) is amended to read as follows:

“(iii) provides not more than a total of 25 extended care service beds (pursuant to an agreement under subsection (f)) and acute care inpatient beds (meeting such standards as the Secretary may establish) for providing inpatient care for a period that does not exceed, as determined on an annual, average basis, 96 hours per patient;”.

(2) CONFORMING AMENDMENT.—Section 1820(f) (42 U.S.C. 1395i-4(f)) is amended by striking “and the number of beds used at any time for

1 acute care inpatient services does not exceed 15
2 beds”.

3 (3) EFFECTIVE DATE.—The amendments made
4 by this subsection shall with respect to designations
5 made on or after October 1, 2004.

6 (b) ELIMINATION OF THE ISOLATION TEST FOR
7 COST-BASED CAH AMBULANCE SERVICES.—

8 (1) ELIMINATION.—

9 (A) IN GENERAL.—Section 1834(l)(8) (42
10 U.S.C. 1395m(l)(8)), as added by section
11 205(a) of BIPA (114 Stat. 2763A–482), is
12 amended by striking the comma at the end of
13 subparagraph (B) and all that follows and in-
14 serting a period.

15 (B) EFFECTIVE DATE.—The amendment
16 made by subparagraph (A) shall apply to serv-
17 ices furnished on or after January 1, 2005.

18 (2) TECHNICAL CORRECTION.—Section 1834(l)
19 (42 U.S.C. 1395m(l)) is amended by redesignating
20 paragraph (8), as added by section 221(a) of BIPA
21 (114 Stat. 2763A–486), as paragraph (9).

22 (c) COVERAGE OF COSTS FOR CERTAIN EMERGENCY
23 ROOM ON-CALL PROVIDERS.—

24 (1) IN GENERAL.—Section 1834(g)(5) (42
25 U.S.C. 1395m(g)(5)) is amended—

(A) in the heading—

(i) by inserting “CERTAIN” before
“EMERGENCY”; and

(ii) by striking “PHYSICIANS” and in-
serting “PROVIDERS”;

(B) by striking “emergency room physi-
cians who are on-call (as defined by the Sec-
retary)” and inserting “physicians, physician
assistants, nurse practitioners, and clinical
nurse specialists who are on-call (as defined by
the Secretary) to provide emergency services”;
and

(C) by striking “physicians’ services” and
inserting “services covered under this title”.

(2) EFFECTIVE DATE.—The amendments made
by paragraph (1) shall apply to costs incurred for
services provided on or after January 1, 2005.

(d) AUTHORIZATION OF PERIODIC INTERIM PAY-
MENT (PIP).—

(1) IN GENERAL.—Section 1815(e)(2) (42
U.S.C. 1395g(e)(2)) is amended—

(A) in subparagraph (C), by striking
“and” after the semicolon at the end;

(B) in subparagraph (D), by adding “and”
after the semicolon at the end; and

1 (C) by inserting after subparagraph (D)
 2 the following new subparagraph:

3 “(E) inpatient critical access hospital services;”.

4 (2) EFFECTIVE DATE.—The amendments made
 5 by paragraph (1) shall apply to payments for inpa-
 6 tient critical access facility services furnished on or
 7 after January 1, 2005.

8 (e) EXCLUSION OF NEW CAHS FROM PPS HOS-
 9 PITAL WAGE INDEX CALCULATION.—Section
 10 1886(d)(3)(E)(i) (42 U.S.C. 1395ww(d)(3)(E)(i)), as
 11 amended by section 402, is amended by inserting after the
 12 first sentence the following new sentence: “In calculating
 13 the hospital wage levels under the preceding sentence ap-
 14 plicable with respect to cost reporting periods beginning
 15 on or after January 1, 2004, the Secretary shall exclude
 16 the wage levels of any facility that became a critical access
 17 hospital prior to the cost reporting period for which such
 18 hospital wage levels are calculated.”.

19 (f) PROVISIONS RELATED TO CERTAIN RURAL
 20 GRANTS.—

21 (1) SMALL RURAL HOSPITAL IMPROVEMENT
 22 PROGRAM.—Section 1820(g) (42 U.S.C. 1395i-4(g))
 23 is amended—

(A) by redesignating paragraph (3)(F) as paragraph (5) and redesignating and indenting appropriately; and

(B) by inserting after paragraph (3) the following new paragraph:

“(4) SMALL RURAL HOSPITAL IMPROVEMENT PROGRAM.—

“(A) GRANTS TO HOSPITALS.—The Secretary may award grants to hospitals that have submitted applications in accordance with subparagraph (B) to assist eligible small rural hospitals (as defined in paragraph (3)(B)) in meeting the costs of reducing medical errors, increasing patient safety, protecting patient privacy, and improving hospital quality and performance.

“(B) APPLICATION.—A hospital seeking a grant under this paragraph shall submit an application to the Secretary on or before such date and in such form and manner as the Secretary specifies.

“(C) AMOUNT OF GRANT.—A grant to a hospital under this paragraph may not exceed \$50,000.

1 “(D) USE OF FUNDS.—A hospital receiv-
2 ing a grant under this paragraph may use the
3 funds for the purchase of computer software
4 and hardware, the education and training of
5 hospital staff, and obtaining technical assist-
6 ance.”.

7 (2) AUTHORIZATION FOR APPROPRIATIONS.—
8 Section 1820(j) (42 U.S.C. 1395i-4(j)) is amended
9 to read as follows:

10 “(j) AUTHORIZATION OF APPROPRIATIONS.—

11 “(1) HI TRUST FUND.—There are authorized to
12 be appropriated from the Federal Hospital Insur-
13 ance Trust Fund for making grants to all States
14 under—

15 “(A) subsection (g), \$25,000,000 in each
16 of the fiscal years 1998 through 2002; and

17 “(B) paragraphs (1) and (2) of subsection
18 (g), \$40,000,000 in each of the fiscal years
19 2004 through 2008.

20 “(2) GENERAL REVENUES.—There are author-
21 ized to be appropriated from amounts in the Treas-
22 ury not otherwise appropriated for making grants to
23 all States under subsection (g)(4), \$25,000,000 in
24 each of the fiscal years 2004 through 2008.”.

(3) REQUIREMENT THAT STATES AWARDED GRANTS CONSULT WITH THE STATE HOSPITAL ASSOCIATION AND RURAL HOSPITALS ON THE MOST APPROPRIATE WAYS TO USE SUCH GRANTS.—

(A) IN GENERAL.—Section 1820(g) (42 U.S.C. 1395i-4(g)), as amended by paragraph (1), is amended by adding at the end the following new paragraph:

“(6) REQUIRED CONSULTATION FOR STATES AWARDED GRANTS.—A State awarded a grant under paragraph (1) or (2) shall consult with the hospital association of such State and rural hospitals located in such State on the most appropriate ways to use the funds under such grant.”.

(B) EFFECTIVE DATE AND APPLICATION.—The amendment made by subparagraph (A) shall take effect on the date of enactment of this Act and shall apply to grants awarded on or after such date and to grants awarded prior to such date to the extent that funds under such grants have not been obligated as of such date.

(g) EXCLUSION OF CERTAIN BEDS FROM BED COUNT AND REMOVAL OF BARRIERS TO ESTABLISHMENT OF DISTINCT PART UNITS.—

1 (1) EXCLUSION OF CERTAIN BEDS FROM BED
 2 COUNT.—Section 1820(c)(2) (42 U.S.C. 1395i-
 3 4(c)(2)) is amended by adding at the end the fol-
 4 lowing:

5 “(E) EXCLUSION OF CERTAIN BEDS FROM
 6 BED COUNT.—In determining the number of
 7 beds of a facility for purposes of applying the
 8 bed limitations referred to in subparagraph
 9 (B)(iii) and subsection (f), the Secretary shall
 10 not take into account any bed of a distinct part
 11 of a psychiatric or rehabilitation unit (described in
 12 the matter following clause (v) of section
 13 1886(d)(1)(B)) of the facility, except that the
 14 total number of beds that are not taken into ac-
 15 count pursuant to this subparagraph with re-
 16 spect to a facility shall not exceed 25.”.

17 (2) REMOVING BARRIERS TO ESTABLISHMENT
 18 OF DISTINCT PART UNITS BY CRITICAL ACCESS HOS-
 19 PITALS.—Section 1886(d)(1)(B) (42 U.S.C.
 20 1395ww(d)(1)(B)) is amended by striking “a distinct
 21 part of the hospital (as defined by the Secretary)”
 22 in the matter following clause (v) and inserting “a
 23 distinct part (as defined by the Secretary) of the
 24 hospital or of a critical access hospital”.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to determinations with respect to distinct part unit status, and with respect to designations, that are made on or after October 1, 2003.

SEC. 406. AUTHORIZING USE OF ARRANGEMENTS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES.

(a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C. 1395x(dd)(5)) is amended by adding at the end the following:

“(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program’s service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

“(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-rou-

tinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.”.

(b) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

“(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after October 1, 2004.

SEC. 407. SERVICES PROVIDED TO HOSPICE PATIENTS BY NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND PHYSICIAN ASSISTANTS.

(a) IN GENERAL.—Section 1812(d)(2)(A) (42 U.S.C. 1395d(d)(2)(A) in the matter following clause (i)(II), is amended—

- (1) by inserting “or services described in section 1861(s)(2)(K)” after “except that clause (i) shall not apply to physicians’ services”; and
- (2) by inserting “, or by a physician assistant, nurse practitioner, or clinical nurse specialist whom

1 is not an employee of the hospice program, and who
2 the individual identifies as the health care provider
3 having the most significant role in the determination
4 and delivery of medical care to the individual at the
5 time the individual makes an election to receive hos-
6 pice care,” after the “(if not an employee of the hos-
7 pice program)”.

8 (b) PERMITTING NURSE PRACTITIONERS, PHYSICIAN

9 ASSISTANTS, AND CLINICAL NURSE SPECIALIST TO RE-

10 VIEW HOSPICE PLANS OF CARE.—Section 1814(a)(7)(B)

11 is amended by inserting “(or by a physician assistant,
12 nurse practitioner or clinical nurse specialist who is not
13 an employee of the hospice program, and whom the indi-
14 vidual identifies as the health care provider having the
15 most significant role in the determination and delivery of
16 medical care to the individual at the time the individual
17 makes an election to receive hospice care)” after “and is
18 periodically reviewed by the individual’s attending physi-
19 cian”.

20 (c) EFFECTIVE DATE.—The amendments made by

21 this section shall apply to hospice care furnished on or
22 after October 1, 2004.

1 **SEC. 408. AUTHORITY TO INCLUDE COSTS OF TRAINING OF**
 2 **PSYCHOLOGISTS IN PAYMENTS TO HOS-**
 3 **PITALS UNDER MEDICARE.**

4 Effective for cost reporting periods beginning on or
 5 after October 1, 2004, for purposes of payments to hos-
 6 pitals under the medicare program under title XVIII of
 7 the Social Security Act for costs of approved educational
 8 activities (as defined in section 413.85 of title 42 of the
 9 Code of Federal Regulations), such approved educational
 10 activities shall include professional educational training
 11 programs, recognized by the Secretary, for psychologists.

12 **SEC. 409. REVISION OF FEDERAL RATE FOR HOSPITALS IN**
 13 **PUERTO RICO.**

14 Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is
 15 amended—

16 (1) in subparagraph (A)—

17 (A) in clause (i), by striking “for dis-
 18 charges beginning on or after October 1, 1997,
 19 50 percent (and for discharges between October
 20 1, 1987, and September 30, 1997, 75 percent)”
 21 and inserting “the applicable Puerto Rico per-
 22 centage (specified in subparagraph (E))”; and

23 (B) in clause (ii), by striking “for dis-
 24 charges beginning in a fiscal year beginning on
 25 or after October 1, 1997, 50 percent (and for
 26 discharges between October 1, 1987, and Sep-

tember 30, 1997, 25 percent)” and inserting

“the applicable Federal percentage (specified in subparagraph (E))”; and

(2) by adding at the end the following new subparagraph:

“(E) For purposes of subparagraph (A), for discharges occurring—

“(i) between October 1, 1987, and September 30, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

“(ii) on or after October 1, 1997, and before October 1, 2004, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

“(iii) on or after October 1, 2004, and before October 1, 2009, the applicable Puerto Rico percentage is 0 percent and the applicable Federal percentage is 100 percent; and

“(iv) on or after October 1, 2009, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent.”.

1 **SEC. 410. EXCEPTION TO INITIAL RESIDENCY PERIOD FOR**
2 **GERIATRIC RESIDENCY OR FELLOWSHIP**
3 **PROGRAMS.**

4 (a) CLARIFICATION OF CONGRESSIONAL INTENT.—
5 Congress intended section 1886(h)(5)(F)(ii) of the Social
6 Security Act (42 U.S.C. 1395ww(h)(5)(F)(ii)), as added
7 by section 9202 of the Consolidated Omnibus Budget Rec-
8 onciliation Act of 1985 (Public Law 99-272), to provide
9 an exception to the initial residency period for geriatric
10 residency or fellowship programs such that, where a par-
11 ticular approved geriatric training program requires a
12 resident to complete 2 years of training to initially become
13 board eligible in the geriatric specialty, the 2 years spent
14 in the geriatric training program are treated as part of
15 the resident's initial residency period, but are not counted
16 against any limitation on the initial residency period.

17 (b) INTERIM FINAL REGULATORY AUTHORITY AND
18 EFFECTIVE DATE.—The Secretary shall promulgate in-
19 terim final regulations consistent with the congressional
20 intent expressed in this section after notice and pending
21 opportunity for public comment to be effective for cost re-
22 porting periods beginning on or after October 1, 2003.

1 **SEC. 411. CLARIFICATION OF CONGRESSIONAL INTENT RE-**
 2 **GARDING THE COUNTING OF RESIDENTS IN A**
 3 **NONPROVIDER SETTING AND A TECHNICAL**
 4 **AMENDMENT REGARDING THE 3-YEAR ROLL-**
 5 **ING AVERAGE AND THE IME RATIO.**

6 (a) CLARIFICATION OF REQUIREMENTS FOR COUNT-
 7 ING RESIDENTS TRAINING IN NONPROVIDER SETTING.—

8 (1) D-GME.—Section 1886(h)(4)(E) (42
 9 U.S.C. 1395ww(h)(4)(E)) is amended by adding at
 10 the end the following new sentence: For purposes of
 11 the preceding sentence time shall only be counted
 12 from the effective date of a written agreement be-
 13 tween the hospital and the entity owning or oper-
 14 ating a nonprovider setting. The effective date of
 15 such written agreement shall be determined in ac-
 16 cordance with generally accepted accounting prin-
 17 ciples. All, or substantially all, of the costs for the
 18 training program in that setting shall be defined as
 19 the residents' stipends and benefits and other costs,
 20 if any, as determined by the parties.”.

21 (2) IME.—Section 1886(d)(5)(B)(iv) (42
 22 U.S.C. 1395ww(d)(5)(B)(iv)) is amended by adding
 23 at the end the following new sentence: For purposes
 24 of the preceding sentence time shall only be counted
 25 from the effective date of a written agreement be-
 26 tween the hospital and the entity owning or oper-

1 ating a nonprovider setting. The effective date of
 2 such written agreement shall be determined in ac-
 3 cordance with generally accepted accounting prin-
 4 ciples. All, or substantially all, of the costs for the
 5 training program in that setting shall be defined as
 6 the residents' stipends and benefits and other costs,
 7 if any, as determined by the parties."

8 (b) LIMITING ONE-YEAR LAG IN THE INDIRECT
 9 MEDICAL EDUCATION (IME) RATIO AND THREE-YEAR
 10 ROLLING AVERAGE IN RESIDENT COUNT FOR IME AND
 11 FOR DIRECT GRADUATE MEDICAL EDUCATION (D-GME)
 12 TO MEDICAL RESIDENCY PROGRAMS.—

13 (1) IME RATIO AND IME ROLLING AVERAGE.—

14 Section 1886(d)(5)(B)(vi) of the Social Security Act
 15 (42 U.S.C. 1395ww(d)(5)(B)(vi)) is amended by
 16 adding at the end the following new sentence: "For
 17 cost reporting periods beginning during fiscal years
 18 beginning on or after October 1, 2004, subclauses
 19 (I) and (II) shall be applied only with respect to a
 20 hospital's approved medical residency training pro-
 21 grams in the fields of allopathic and osteopathic
 22 medicine."

23 (2) D-GME ROLLING AVERAGE.—Section
 24 1886(h)(4)(G) of the Social Security Act (42 U.S.C.

1395ww(h)(4)(G)) is amended by adding at the end
the following new clause:

~~insertion~~“(iv) APPLICATION FOR FISCAL YEAR
2004 AND SUBSEQUENT YEARS.—For cost
reporting periods beginning during fiscal
years beginning on or after October 1,
2004, clauses (i) through (iii) shall be ap-
plied only with respect to a hospital’s ap-
proved medical residency training program
in the fields of allopathic and osteopathic
medicine.”. ~~it follows the same pattern as~~

**SEC. 412. LIMITATION ON CHARGES FOR INPATIENT HOS-
PITAL CONTRACT HEALTH SERVICES PRO-
VIDED TO INDIANS BY MEDICARE PARTICI-
PATING HOSPITALS.** ~~insertion: same as sec. 401~~

(a) IN GENERAL.—Section 1866(a)(1) (42 U.S.C.
1395cc(a)(1)) is amended—

(1) in subparagraph (R), by striking “and” at
the end; ~~insertion: in benefit~~

(2) in subparagraph (S), by striking the period
and inserting “, and”; and ~~insertion: and~~

(3) by adding at the end the following new sub-
paragraph: ~~insertion: same as sec. 401~~

“(T) in the case of hospitals which furnish
inpatient hospital services for which payment

1 may be made under this title, to be a partici-
2 pating provider of medical care—

3 “(i) under the contract health services
4 program funded by the Indian Health
5 Service and operated by the Indian Health
6 Service, an Indian tribe, or tribal organiza-
7 tion (as those terms are defined in section
8 4 of the Indian Health Care Improvement
9 Act), with respect to items and services
10 that are covered under such program and
11 furnished to an individual eligible for such
12 items and services under such program;
13 and

14 “(ii) under a program funded by the
15 Indian Health Service and operated by an
16 urban Indian organization with respect to
17 the purchase of items and services for an
18 eligible urban Indian (as those terms are
19 defined in such section 4),

20 in accordance with regulations promulgated by
21 the Secretary regarding admission practices,
22 payment methodology, and rates of payment
23 (including the acceptance of no more than such
24 payment rate as payment in full for such items
25 and services).”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 this section shall apply as of a date specified by the Sec-
3 retary of Health and Human Services (but in no case later
4 than 6 months after the date of enactment of this Act)
5 to medicare participation agreements in effect (or entered
6 into) on or after such date.

7 **SEC. 413. GAO STUDY AND REPORT ON APPROPRIATENESS**
8 **OF PAYMENTS UNDER THE PROSPECTIVE**
9 **PAYMENT SYSTEM FOR INPATIENT HOSPITAL**
10 **SERVICES.**

11 (a) STUDY.—The Comptroller General of the United
12 States, using the most current data available, shall con-
13 duct a study to determine—

14 (1) the appropriate level and distribution of
15 payments in relation to costs under the prospective
16 payment system under section 1886 of the Social
17 Security Act (42 U.S.C. 1395ww) for inpatient hos-
18 pital services furnished by subsection (d) hospitals
19 (as defined in subsection (d)(1)(B) of such section);
20 and

21 (2) whether there is a need to adjust such pay-
22 ments under such system to reflect legitimate dif-
23 ferences in costs across different geographic areas,
24 kinds of hospitals, and types of cases.

(b) REPORT.—Not later than 24 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the study conducted under subsection (a) together with such recommendations for legislative and administrative action as the Comptroller General determines appropriate.

SEC. 414. RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT OF RURAL COMMUNITY HOSPITAL (RCH) DEMONSTRATION PROGRAM.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program to test the feasibility and advisability of the establishment of rural community hospitals that furnish rural community hospital services to medicare beneficiaries.

(2) DESIGNATION OF RCHS.—

(A) APPLICATION.—Each hospital that is located in a demonstration area described in subparagraph (C) that desires to participate in the demonstration program under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(B) DESIGNATION.—The Secretary shall designate any hospital that is located in a dem-

onstration area described in subparagraph (C), submits an application in accordance with subparagraph (A), and meets the other requirements of this section as a rural community hospital for purposes of the demonstration program.

(C) DEMONSTRATION AREAS.—There shall be four demonstration areas within this program. Two of these demonstration areas described in this subparagraph shall include Kansas and Nebraska.

(3) DURATION.—The Secretary shall conduct the demonstration program under this section for a 5-year period.

(4) IMPLEMENTATION.—The Secretary shall implement the demonstration program not later than January 1, 2005, but may not implement the program before October 1, 2004.

(b) PAYMENT.—

(1) INPATIENT HOSPITAL SERVICES.—The amount of payment under the demonstration program for inpatient hospital services furnished in a rural community hospital, other than such services furnished in a psychiatric or rehabilitation unit of the hospital which is a distinct part, is, at the elec-

1 tion of the hospital in the application referred to in
2 subsection (a)(2)(A)—

3 (A) the reasonable costs of providing such
4 services, without regard to the amount of the
5 customary or other charge; or

6 (B) the amount of payment provided for
7 under the prospective payment system for inpa-
8 tient hospital services under section 1886(d) of
9 the Social Security Act (42 U.S.C. 1395ww(d)).

10 (2) OUTPATIENT SERVICES.—The amount of
11 payment under the demonstration program for out-
12 patient services furnished in a rural community hos-
13 pital is, at the election of the hospital in the applica-
14 tion referred to in subsection (a)(2)(A)—

15 (A) the reasonable costs of providing such
16 services, without regard to the amount of the
17 customary or other charge and any limitation
18 under section 1861(v)(1)(U) of the Social Secu-
19 rity Act (42 U.S.C. 1395x(v)(1)(U)); or

20 (B) the amount of payment provided for
21 under the prospective payment system for cov-
22 ered OPD services under section 1833(t) of the
23 Social Security Act (42 U.S.C. 1395l(t)).

24 (3) HOME HEALTH SERVICES.—In determining
25 payments under the demonstration program for

home health services furnished by a qualified RCH-
 based home health agency (as defined in paragraph
 (2))—

(A) the agency may make a one-time elec-
 tion to waive application of the prospective pay-
 ment system established under section 1895 of
 the Social Security Act (42 U.S.C. 1395fff) to
 such services furnished by the agency; and

(B) in the case of such an election, pay-
 ment shall be made on the basis of the reason-
 able costs incurred in furnishing such services
 as determined under section 1861(v) of the So-
 cial Security Act (42 U.S.C. 1395x(v)), but
 without regard to the amount of the customary
 or other charges with respect to such services or
 the limitations established under paragraph
 (1)(L) of such section.

(4) CONSOLIDATED BILLING.—The Secretary
 shall permit consolidated billing under section
 1842(b)(6)(E) of the Social Security Act (42 U.S.C.
 1395u(b)(6)(E)).

(5) EXEMPTION FROM 30 PERCENT REDUCTION
 IN REIMBURSEMENT FOR BAD DEBT.—In deter-
 mining the reasonable costs for rural community

1 hospitals, section 1861(v)(1)(T) of the Social Secu-
 2 rity Act (42 U.S.C. 1395x(v)(1)(T)) shall not apply.

3 (6) BENEFICIARY COST-SHARING FOR OUT-
 4 PATIENT SERVICES.—The amounts of beneficiary
 5 cost-sharing for outpatient services furnished in a
 6 rural community hospital under the demonstration
 7 program shall be as follows:

8 (A) For items and services that would have
 9 been paid under section 1833(t) of the Social
 10 Security Act (42 U.S.C. 1395l(t)) if provided
 11 by a hospital, the amount of cost-sharing deter-
 12 mined under paragraph (8) of such section.

13 (B) For items and services that would
 14 have been paid under section 1833(h) of such
 15 Act (42 U.S.C. 1395l(h)) if furnished by a pro-
 16 vider or supplier, no cost-sharing shall apply.

17 (C) For all other items and services, the
 18 amount of cost-sharing that would apply to the
 19 item or service under the methodology that
 20 would be used to determine payment for such
 21 item or service if provided by a physician, pro-
 22 vider, or supplier, as the case may be.

23 (7) RETURN ON EQUITY.—

24 (A) IN GENERAL.—Notwithstanding sub-
 25 paragraph (P)(i) and (S)(i) of section

1861(v)(1) of the Social Security Act (42 U.S.C. 1395x(v)(1)) and section 1886(g)(2) of such Act (42 U.S.C. 1395ww(g)(2)), in determining the reasonable costs of the services described in subclause (II) furnished by a rural community hospital for payment of a return on equity capital at a rate of return equal to 150 percent of the average specified in section 1861(v)(1)(P)(i) of such Act (42 U.S.C. 1395x(v)(1)(P)(i)).

(B) SERVICES DESCRIBED.—The services referred to in subclause (I) are rural community hospital services.

(C) DISREGARD OF PROPRIETARY PROVIDER STATUS.—Payment under the demonstration program shall be made without regard to whether a provider is a proprietary provider.

(8) REMOVING BARRIERS TO ESTABLISHMENT OF DISTINCT PART UNITS BY RCH FACILITIES.—Notwithstanding section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)), the Secretary shall permit rural community hospitals to establish distinct part units for purposes of applying such section.

1 (c) FUNDING.—

2 (1) IN GENERAL.—The Secretary shall provide
3 for the transfer from the Federal Hospital Insurance
4 Trust Fund under section 1817 of the Social Secu-
5 rity Act (42 U.S.C. 1395i) and the Federal Supple-
6 mentary Insurance Trust Fund established under
7 section 1841 of such Act (42 U.S.C. 1395t), in such
8 proportion as the Secretary determines to be appro-
9 priate, of such funds as are necessary for the costs
10 of carrying out the demonstration program under
11 this section.

12 (2) BUDGET NEUTRALITY.—In conducting the
13 demonstration program under this section, the Sec-
14 retary shall ensure that the aggregate payments
15 made by the Secretary do not exceed the amount
16 which the Secretary would have paid if the dem-
17 onstration program under this section was not im-
18 plemented.

19 (d) WAIVER AUTHORITY.—The Secretary may waive
20 such requirements of titles XI and XVIII of the Social
21 Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as
22 may be necessary for the purpose of carrying out the dem-
23 onstration program under this section.

24 (e) REPORT.—Not later than 6 months after the
25 completion of the demonstration program under this sec-

tion, the Secretary shall submit to Congress a report on such program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

(f) DEFINITIONS.—In this section:

(1) RURAL COMMUNITY HOSPITAL.—

(A) IN GENERAL.—The term “rural community hospital” means a hospital (as defined in section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e))) that—

(i) is located in a rural area (as defined in section 1886(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D))) or treated as being so located pursuant to section 1886(d)(8)(E) of such Act (42 U.S.C. 1395ww(d)(8)(E));

(ii) subject to subparagraph (B), has less than 51 acute care inpatient beds, as reported in its most recent cost report;

(iii) makes available 24-hour emergency care services;

(iv) subject to subparagraph (C), has a provider agreement in effect with the Secretary and is open to the public as of January 1, 2003; and

1 (v) applies to the Secretary for such
2 designation.

3 (B) TREATMENT OF PSYCHIATRIC AND RE-
4 HABILITATION UNITS.—For purposes of para-
5 graph (1)(B), beds in a psychiatric or rehabili-
6 tation unit of the hospital which is a distinct
7 part of the hospital shall not be counted.

8 (C) TYPES OF HOSPITALS THAT MAY PAR-
9 TICIPATE.—Subparagraph (1)(D) shall not be
10 construed to prohibit any of the following from
11 qualifying as a rural community hospital:

12 (i) A replacement facility (as defined
13 by the Secretary in regulations in effect on
14 January 1, 2003) with the same service
15 area (as defined by the Secretary in regu-
16 lations in effect on such date).

17 (ii) A facility obtaining a new provider
18 number pursuant to a change of owner-
19 ship.

20 (iii) A facility which has a binding
21 written agreement with an outside, unre-
22 lated party for the construction, recon-
23 struction, lease, rental, or financing of a
24 building as of January 1, 2003.

(D) INCLUSION OF CAHS.—Nothing in this subsection shall be construed as prohibiting a critical access hospital from qualifying as a rural community hospital if the critical access hospital meets the conditions otherwise applicable to hospitals under section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e)) and section 1866 of such Act (42 U.S.C. 1395cc).

(2) QUALIFIED RCH-BASED HOME HEALTH AGENCY DEFINED.—The term “qualified RCH-based home health agency” is a home health agency that is a provider-based entity (as defined in section 404 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106–554; Appendix F, 114 Stat. 2763A–506)) of a rural community hospital that is located—

(A) in a county in which no main or branch office of another home health agency is located; or

(B) at least 35 miles from any main or branch office of another home health agency.

**SEC. 415. CRITICAL ACCESS HOSPITAL IMPROVEMENT
DEMONSTRATION PROGRAM.**

(a) ESTABLISHMENT OF CRITICAL ACCESS HOSPITAL DEMONSTRATION PROGRAM.—

1 (1) IN GENERAL.—The Secretary shall establish
2 a demonstration program to test various methods to
3 improve the critical access hospital program under
4 section 1820 of the Social Security Act (42 U.S.C.
5 1395i-4).

6 (2) CRITICAL ACCESS HOSPITAL IMPROVE-
7 MENT.—In conducting the demonstration program
8 under this section, the Secretary shall apply rules
9 with respect to critical access hospitals participating
10 in the program as follows:

11 (A) EXCLUSION OF CERTAIN BEDS FROM
12 BED COUNT.—In determining the number of
13 beds of a facility for purposes of applying the
14 bed limitations referred to in subsections
15 (c)(2)(B)(iii) and (f) of section 1820 of the So-
16 cial Security Act (42 U.S.C. 1395i-4), the Sec-
17 retary shall not take into account any bed of a
18 distinct part psychiatric or rehabilitation unit
19 (described in the matter following clause (v) of
20 section 1886(d)(1)(B) of such Act (42 U.S.C.
21 1395ww(d)(1)(B))) of the facility, except that
22 the total number of beds that are not taken
23 into account pursuant to this subparagraph
24 with respect to a facility shall not exceed 10.

(B) EXCLUSION FROM HOME HEALTH
PPS.—Notwithstanding section 1895 of the Social Security Act (42 U.S.C. 1395fff), in determining payments under the demonstration program for home health services furnished by a home health agency that is owned and operated by a critical access hospital participating in the demonstration program—

(i) the agency may make an election to waive application of the prospective payment system established under such section to such services furnished by the agency; and

(ii) in the case of such an election, payment shall be made on the basis of the reasonable costs incurred in furnishing such services as determined under section 1861(v), but without regard to the amount of the customary or other charges with respect to such services or the limitations established under paragraph (1)(L) of such section.

(C) EXEMPTION OF CAH FACILITIES FROM
PPS.—Notwithstanding section 1888(e) of the Social Security Act (42 U.S.C. 1395yy(e)), in

determining payments under this part for covered skilled nursing facility services furnished by a skilled nursing facility that is a distinct part unit of a critical access hospital participating in the demonstration program or is owned and operated by a critical access hospital participating in the demonstration program—

(i) the prospective payment system established under such section shall not apply; and

(ii) payment shall be made on the basis of the reasonable costs incurred in furnishing such services as determined under section 1861(v) of such Act (42 U.S.C. 1395x(v)), but without regard to the amount of the customary or other charges with respect to such services.

(D) CONSOLIDATED BILLING.—The Secretary shall permit consolidated billing under section 1842(b)(6)(E) of the Social Security Act (42 U.S.C. 1395u(b)(6)(E)).

(E) EXEMPTION OF CERTAIN DISTINCT PART PSYCHIATRIC OR REHABILITATION UNITS FROM COST LIMITS.—Notwithstanding section 1886(b) of the Social Security Act (42 U.S.C.

1 1395ww(b)), in determining payments under
 2 the demonstration program for inpatient hos-
 3 pital services furnished by a distinct part psy-
 4 chiatric or rehabilitation unit (described in the
 5 matter following section 1886(d)(1)(B)(v) of
 6 such Act (42 U.S.C. 1395ww(d)(1)(B)(v))) of a
 7 critical access hospital participating in the dem-
 8 onstration program—

9 ~~transferred~~(i) the limits imposed under the pre-
 10 ceeding paragraphs of this subsection shall
 11 not apply; and

12 (ii) payment shall be made on the
 13 basis of the reasonable costs incurred in
 14 furnishing such services as determined
 15 under section 1861(v) of such Act (42
 16 U.S.C. 1395x(v)), but without regard to
 17 the amount of the customary or other
 18 charges with respect to such services.

19 (F) RETURN ON EQUITY.—

20 (i) IN GENERAL.—Notwithstanding
 21 subparagraph (P)(i) and (S)(i) of section
 22 1861(v)(1) of the Social Security Act (42
 23 U.S.C. 1395x(v)(1)) and section
 24 1886(g)(2) of such Act (42 U.S.C.
 25 1395ww(g)(2)), in determining the reason-

able costs of the services described in subclause (II) furnished by a critical access hospital participating in the demonstration program for payment of a return on equity capital at a rate of return equal to 150 percent of the average specified in section 1861(v)(1)(P)(i) of such Act (42 U.S.C. 1395x(v)(1)(P)(i)).

(ii) SERVICES DESCRIBED.—The services referred to in subclause (I) are inpatient critical access hospital services, outpatient critical access hospital services, extended care services, posthospital extended care services, home health services, ambulance services, and inpatient hospital services.

(iii) DISREGARD OF PROPRIETARY PROVIDER STATUS.—Payment under the demonstration program shall be made without regard to whether a provider is a proprietary provider.

(G) REMOVING BARRIERS TO ESTABLISHMENT OF DISTINCT PART UNITS BY CAH FACILITIES.—Notwithstanding section 1886(d)(1)(B) of the Social Security Act (42

1 U.S.C. 1395ww(d)(1)(B)), the Secretary shall
2 permit critical access hospitals participating in
3 the demonstration program to establish distinct
4 part units for purposes of applying such sec-
5 tion.

6 (3) PARTICIPATION OF CAHS.—

7 (A) APPLICATION.—Each critical access
8 hospital that is located in a demonstration area
9 described in subparagraph (C) that desires to
10 participate in the demonstration program under
11 this section shall submit an application to the
12 Secretary at such time, in such manner, and
13 containing such information as the Secretary
14 may require.

15 (B) PARTICIPATION.—The Secretary shall
16 permit any critical access hospital that is lo-
17 cated in a demonstration area described in sub-
18 paragraph (C), submits an application in ac-
19 cordance with subparagraph (A), and meets the
20 other requirements of this section to participate
21 in the demonstration program.

22 (C) DEMONSTRATION AREAS.—There shall
23 be four demonstration areas within this pro-
24 gram. Two of these demonstration areas de-

1 scribed in this subparagraph shall include Kan-
2 sas and Nebraska.

3 (4) DURATION.—The Secretary shall conduct
4 the demonstration program under this section for a
5 5-year period.

6 (5) IMPLEMENTATION.—The Secretary shall
7 implement the demonstration program not later than
8 January 1, 2005, but may not implement the pro-
9 gram before October 1, 2004.

10 (b) FUNDING.—

11 (1) IN GENERAL.—The Secretary shall provide
12 for the transfer from the Federal Hospital Insurance
13 Trust Fund under section 1817 of the Social Secu-
14 rity Act (42 U.S.C. 1395i) and the Federal Supple-
15 mentary Insurance Trust Fund established under
16 section 1841 of such Act (42 U.S.C. 1395t), in such
17 proportion as the Secretary determines to be appro-
18 priate, of such funds as are necessary for the costs
19 of carrying out the demonstration program under
20 this section.

21 (2) BUDGET NEUTRALITY.—In conducting the
22 demonstration program under this section, the Sec-
23 retary shall ensure that the aggregate payments
24 made by the Secretary do not exceed the amount
25 which the Secretary would have paid if the dem-

onstration program under this section was not implemented.

(c) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

(d) REPORT.—Not later than 6 months after the completion of the demonstration program under this section, the Secretary shall submit to Congress a report on such program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

SEC. 416. TREATMENT OF GRANDFATHERED LONG-TERM CARE HOSPITALS.

(a) IN GENERAL.—The last sentence of section 1886(d)(1)(B) is amended by inserting “, and the Secretary may not impose any special conditions on the operation, size, number of beds, or location of any hospital so classified for continued participation under this title or title XIX or for continued classification as a hospital described in clause (iv)” before the period at the end.

(b) TREATMENT OF PROPOSED REVISION.—The Secretary shall not adopt the proposed revision to section 412.22(f) of title 42, Code of Federal Regulations con-

1 tained in 68 Federal Register 27154 (May 19, 2003) or
 2 any revision reaching the same or substantially the same
 3 result as such revision.

4 (c) EFFECTIVE DATE.—The amendment made by,
 5 and provisions of, this section shall apply to cost reporting
 6 periods ending on or after December 31, 2002.

7 **SEC. 417. TREATMENT OF CERTAIN ENTITIES FOR PUR-**
 8 **POSES OF PAYMENTS UNDER THE MEDICARE**
 9 **PROGRAM.**

10 (a) PAYMENTS TO HOSPITALS.—
 11 (1) IN GENERAL.—Notwithstanding any other
 12 provision of law, effective for discharges occurring
 13 on or after October 1, 2003, for purposes of making
 14 payments to hospitals (as defined in section 1886(d)
 15 and 1833(t) of the Social Security Act (42 U.S.C.
 16 1395(d)) under the medicare program under title
 17 XVIII of such Act (42 U.S.C. 1395 et seq.), Iredell
 18 County, North Carolina, and Rowan County, North
 19 Carolina, are deemed to be located in the Charlotte-
 20 Gastonia-Rock Hill, North Carolina, South Carolina
 21 Metropolitan Statistical Area.

22 (2) BUDGET NEUTRAL WITHIN NORTH CARO-
 23 LINA.—The Secretary shall adjust the area wage
 24 index referred to in paragraph (1) with respect to
 25 payments to hospitals located in North Carolina in

1 a manner which assures that the total payments
2 made under section 1886(d) of the Social Security
3 Act (42 U.S.C., 1395(w)(d)) in a fiscal year for
4 the operating cost of inpatient hospital services are
5 not greater or less than the total of such payments
6 that would have been made in the year if this sub-
7 section had not been enacted.

8 (b) PAYMENTS TO SKILLED NURSING FACILITIES
9 AND HOME HEALTH AGENCIES.—

10 (1) IN GENERAL.—Notwithstanding any other
11 provision of law, effective beginning October 1,
12 2003, for purposes of making payments to skilled
13 nursing facilities (SNFs) and home health agencies
14 (as defined in sections 1861(j) and 1861(o) of the
15 Social Security Act (42 U.S.C. 1395x(j); 1395x(o))
16 under the medicare program under title XVIII of
17 such Act, Iredell County, North Carolina, and
18 Rowan County, North Carolina, are deemed to be lo-
19 cated in the Charlotte-Gastonia-Rock Hill, North
20 Carolina, South Carolina Metropolitan Statistical
21 Area.

22 (2) APPLICATION AND BUDGET NEUTRAL WITH-
23 IN NORTH CAROLINA.—Effective for fiscal year
24 2004, the skilled nursing facility PPS and home
25 health PPS rates for Iredell County, North Carolina,

1 and Rowan County, North Carolina, will be updated
 2 by the prefloor, prereclassified hospital wage index
 3 available for the Charlotte-Gastonia-Rock Hill,
 4 North Carolina, South Carolina Metropolitan Statis-
 5 tical Area. This subsection shall be implemented in
 6 a budget neutral manner, using a methodology that
 7 ensures that the total amount of expenditures for
 8 skilled nursing facility services and home health
 9 services in a year does not exceed the total amount
 10 of expenditures that would have been made in the
 11 year if this subsection had not been enacted. Re-
 12 quired adjustments by reason of the preceding sen-
 13 tence shall be done with respect to skilled nursing
 14 facilities and home health agencies located in North
 15 Carolina.

16 (c) CONSTRUCTION.—The provisions of this section
 17 shall have no effect on the amount of payments made
 18 under title XVIII of the Social Security Act to entities
 19 located in States other than North Carolina.

20 **SEC. 418. REVISION OF THE INDIRECT MEDICAL EDU-**
 21 **CATION (IME) ADJUSTMENT PERCENTAGE.**

22 (a) IN GENERAL.—Section 1886(d)(5)(B)(ii) (42
 23 U.S.C. 1395ww(d)(5)(B)(ii)) is amended—

24 by striking (1) in subclause (VI), by striking “and” after
 25 the semicolon at the end;

(2) in subclause (VII)—

(A) by striking “on or after October 1, 2002” and inserting “during fiscal year 2003”; and

(B) by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following new subclauses:

“(VIII) during each of fiscal years 2004 and 2005, ‘c’ is equal to 1.36; and

“(IX) on or after October 1, 2005, ‘c’ is equal to 1.355.”.

(b) CONFORMING AMENDMENT RELATING TO DE-TERMINATION OF STANDARDIZED AMOUNT.—Section 1886(d)(2)(C)(i) (42 U.S.C. 1395ww(d)(2)(C)(i)) is amended—

(1) by striking “1999 or” and inserting “1999,”; and

(2) by inserting “, or the Prescription Drug and Medicare Improvement Act of 2003” after “2000”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to discharges occurring on or after October 1, 2003.

1 **SEC. 419. CALCULATION OF WAGE INDICES FOR HOS-**
 2 **PITALS.**

3 Notwithstanding any other provision of law, in the
 4 calculation of a wage index in a State for purposes of mak-
 5 ing payments for discharges occurring during fiscal year
 6 2004, the Secretary may waive such other criteria for re-
 7 classification, as deemed appropriate by the Secretary.

8 **SEC. 420. CONFORMING CHANGES REGARDING FEDERALLY**
 9 **QUALIFIED HEALTH CENTERS.**

10 Section 1833(a)(3) (42 U.S.C. 1395l(a)(3)) is
 11 amended by inserting “(which regulations shall exclude
 12 any cost incurred for the provision of services pursuant
 13 to a contract with an eligible entity (as defined in section
 14 1860D(4)) operating a Medicare Prescription Drug plan
 15 or with an entity with a contract under section 1860D-
 16 13(e), for which payment is made by the entity)” after
 17 “the Secretary may prescribe in regulations”.

18 **SEC. 420A. INCREASE FOR HOSPITALS WITH DISPROPOR-**
 19 **TIONATE INDIGENT CARE REVENUES.**

20 (a) DISPROPORTIONATE SHARE ADJUSTMENT PER-
 21 CENTAGE.—Section 1886(d)(5)(F)(iii) (42 U.S.C.
 22 1395ww(d)(5)(F)(iii)) is amended by striking “35 per-
 23 cent” and inserting “35 percent (or, for discharges occur-
 24 ring on or after October 1, 2003, 40 percent)”.

25 (b) CAPITAL COSTS.—Section 1886(g)(1)(B) (42
 26 U.S.C. 1395ww(g)(1)(B)) is amended—

1 (1) in clause (iii), by striking “and” at the end;

2 (2) in clause (iv), by striking the period at the

3 end and inserting “, and”; and

4 (3) by adding at the end the following new

5 clause:

6 “(v) in the case of cost reporting periods begin-

7 ning on or after October 1, 2003, shall provide for

8 a disproportionate share adjustment in the same

9 manner as section 1886(d)(5)(F)(iii).”.

10 **SEC. 420B. TREATMENT OF GRANDFATHERED LONG-TERM**

11 **CARE HOSPITALS.**

12 (a) IN GENERAL.—The last sentence of section

13 1886(d)(1)(B) is amended by inserting “, and the Sec-

14 retary may not impose any special conditions on the oper-

15 ation, size, number of beds, or location of any hospital so

16 classified for continued participation under this title or

17 title XIX or for continued classification as a hospital de-

18 scribed in clause (iv)” before the period at the end.

19 (b) TREATMENT OF PROPOSED REVISION.—The Sec-

20 retary shall not adopt the proposed revision to section

21 412.22(f) of title 42, Code of Federal Regulations con-

22 tained in 68 Federal Register 27154 (May 19, 2003) or

23 any revision reaching the same or substantially the same

24 result as such revision.

(c) EFFECTIVE DATE.—The amendment made by, and provisions of, this section shall apply to cost reporting periods ending on or after December 31, 2002.

Subtitle B—Provisions Relating to Part B

SEC. 421. ESTABLISHMENT OF FLOOR ON GEOGRAPHIC ADJUSTMENTS OF PAYMENTS FOR PHYSICIANS' SERVICES.

Section 1848(e)(1) (42 U.S.C. 1395w-4(e)(1)) is amended—

(1) in subparagraph (A), by striking “subparagraphs (B) and (C)” and inserting “subparagraphs (B), (C), (E), and (F)”; and

(2) by adding at the end the following new subparagraphs:

“(E) FLOOR FOR WORK GEOGRAPHIC INDICES.—

“(i) IN GENERAL.—For purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2008, after calculating the work geographic indices in subparagraph (A)(iii), the Secretary shall increase the work geographic index to the work floor index for

any locality for which such geographic index is less than the work floor index.

~~(iii)~~“(ii) WORK FLOOR INDEX.—For purposes of clause (i), the term ‘applicable floor index’ means—

~~(i)~~“(I) 0.980 with respect to services furnished during 2004; and

~~(ii)~~“(II) 1.000 for services furnished during 2005, 2006, and 2007.”

“(F) FLOOR FOR PRACTICE EXPENSE AND MALPRACTICE GEOGRAPHIC INDICES.—For purposes of payment for services furnished on or after January 1, 2005, and before January 1, 2008, after calculating the practice expense and malpractice indices in clauses (i) and (ii) of subparagraph (A) and in subparagraph (B), the Secretary shall increase any such index to 1.00 for any locality for which such index is less than 1.00.”.

SEC. 422. MEDICARE INCENTIVE PAYMENT PROGRAM IMPROVEMENTS.

(a) PROCEDURES FOR SECRETARY, AND NOT PHYSICIANS, TO DETERMINE WHEN BONUS PAYMENTS UNDER MEDICARE INCENTIVE PAYMENT PROGRAM SHOULD BE

1 MADE.—Section 1833(m) (42 U.S.C. 1395l(m)) is amend-
 2 ed—

3 (1) by inserting “(1)” after “(m)”; and

4 (2) by adding at the end the following new
 5 paragraph:

6 “(2) The Secretary shall establish procedures under
 7 which the Secretary, and not the physician furnishing the
 8 service, is responsible for determining when a payment is
 9 required to be made under paragraph (1).”.

10 (b) EDUCATIONAL PROGRAM REGARDING THE MEDI-
 11 CARE INCENTIVE PAYMENT PROGRAM.—The Secretary
 12 shall establish and implement an ongoing educational pro-
 13 gram to provide education to physicians under the medi-
 14 care program on the medicare incentive payment program
 15 under section 1833(m) of the Social Security Act (42
 16 U.S.C. 1395l(m)).

17 (c) ONGOING GAO STUDY AND ANNUAL REPORT ON
 18 THE MEDICARE INCENTIVE PAYMENT PROGRAM.—

19 (1) ONGOING STUDY.—The Comptroller Gen-
 20 eral of the United States shall conduct an ongoing
 21 study on the medicare incentive payment program
 22 under section 1833(m) of the Social Security Act
 23 (42 U.S.C. 1395l(m)). Such study shall focus on
 24 whether such program increases the access of medi-
 25 care beneficiaries who reside in an area that is des-

ignated (under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A))) as a health professional shortage area to physicians' services under the medicare program.

(2) ANNUAL REPORTS.—Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Comptroller General of the United States shall submit to Congress a report on the study conducted under paragraph (1), together with recommendations as the Comptroller General considers appropriate.

SEC. 423. EXTENSION OF HOLD HARMLESS PROVISIONS FOR SMALL RURAL HOSPITALS AND TREATMENT OF CERTAIN SOLE COMMUNITY HOSPITALS TO LIMIT DECLINE IN PAYMENT UNDER THE OPD PPS.

(a) SMALL RURAL HOSPITALS.—Section 1833(t)(7)(D)(i) (42 U.S.C. 1395l(t)(7)(D)(i)) is amended by inserting “and during 2006” after “2004,”.

(b) SOLE COMMUNITY HOSPITALS.—Section 1833(t)(7)(D) (42 U.S.C. 1395l(t)(7)(D)) is amended by adding at the end the following:

“(iii) TEMPORARY TREATMENT FOR SOLE COMMUNITY HOSPITALS.—In the case of a sole community hospital (as de-

1 fined in section 1886(d)(5)(D)(iii)) located
 2 in a rural area, for covered OPD services
 3 furnished in 2006, for which the PPS
 4 amount is less than the pre-BBA amount,
 5 the amount of payment under this sub-
 6 section shall be increased by the amount of
 7 such difference.”.

8 **SEC. 424. INCREASE IN PAYMENTS FOR CERTAIN SERVICES**
 9 **FURNISHED BY SMALL RURAL AND SOLE**
 10 **COMMUNITY HOSPITALS UNDER MEDICARE**
 11 **PROSPECTIVE PAYMENT SYSTEM FOR HOS-**
 12 **PITAL OUTPATIENT DEPARTMENT SERVICES.**

13 (a) INCREASE.—

14 (1) IN GENERAL.—In the case of an applicable
 15 covered OPD service (as defined in paragraph (2))
 16 that is furnished by a hospital described in clause (i)
 17 or (iii) of paragraph (7)(D) of section 1833(t) of the
 18 Social Security Act (42 U.S.C. 1395l(t)), as amend-
 19 ed by section 424, on or after January 1, 2005, and
 20 before January 1, 2008, the Secretary shall increase
 21 the medicare OPD fee schedule amount (as deter-
 22 mined under paragraph (4)(A) of such section) that
 23 is applicable for such service in that year (deter-
 24 mined without regard to any increase under this sec-
 25 tion in a previous year) by 5 percent.

(2) APPLICABLE COVERED OPD SERVICES DEFINED.—For purposes of this section, the term “applicable covered OPD service” means a covered clinic or emergency room visit that is classified within the groups of covered OPD services (as defined in paragraph (1)(B) of section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t))) established under paragraph (2)(B) of such section.

(b) NO EFFECT ON COPAYMENT AMOUNT.—The Secretary shall compute the copayment amount for applicable covered OPD services under section 1833(t)(8)(A) of the Social Security Act (42 U.S.C. 1395l(t)(8)(A)) as if this section had not been enacted.

(c) NO EFFECT ON INCREASE UNDER HOLD HARMLESS OR OUTLIER PROVISIONS.—The Secretary shall apply the temporary hold harmless provision under clause (i) and (iii) of paragraph (7)(D) of section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) and the outlier provision under paragraph (5) of such section as if this section had not been enacted.

(d) WAIVING BUDGET NEUTRALITY AND NO REVISION OR ADJUSTMENTS.—The Secretary shall not make any revision or adjustment under subparagraph (A), (B), or (C) of section 1833(t)(9) of the Social Security Act (42

1 U.S.C. 1395l(t)(9)) because of the application of sub-
 2 section (a)(1).

3 (e) NO EFFECT ON PAYMENTS AFTER INCREASE PE-
 4 RIOD ENDS.—The Secretary shall not take into account
 5 any payment increase provided under subsection (a)(1) in
 6 determining payments for covered OPD services (as de-
 7 fined in paragraph (1)(B) of section 1833(t) of the Social
 8 Security Act (42 U.S.C. 1395l(t))) under such section that
 9 are furnished after January 1, 2008.

10 (f) TECHNICAL AMENDMENT.—Section
 11 1833(t)(2)(B) (42 U.S.C. 1395l(t)(2)(B)) is amended by
 12 inserting “(and periodically revise such groups pursuant
 13 to paragraph (9)(A))” after “establish groups”.

14 **SEC. 425. TEMPORARY INCREASE FOR GROUND AMBU-**
 15 **LANCE SERVICES.**

16 Section 1834(l) (42 U.S.C. 1395m(l)), as amended
 17 by section 405(b)(2), is amended by adding at the end
 18 the following new paragraphs:

19 “(10) TEMPORARY INCREASE FOR GROUND AM-
 20 BULANCE SERVICES.—

21 “(A) IN GENERAL.—Notwithstanding any
 22 other provision of this subsection, in the case of
 23 ground ambulance services furnished on or
 24 after January 1, 2005, and before January 1,

2008, for which the transportation originates
in—

“(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after application of any increase under such paragraph, shall be increased by 5 percent; and

“(ii) an area not described in clause (i), the fee schedule established under this section shall provide that the rate for the service otherwise established shall be increased by 2 percent.

“(B) APPLICATION OF INCREASED PAYMENTS AFTER 2007.—The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished on or after the period specified in such subparagraph.

“(11) CONVERSION FACTOR ADJUSTMENTS.—The Secretary shall not adjust downward the conversion factor in any year because of an evaluation of the prior year conversion factor.”.

1 **SEC. 426. ENSURING APPROPRIATE COVERAGE OF AIR AM-**
2 **BULANCE SERVICES UNDER AMBULANCE FEE**
3 **SCHEDULE.**

4 (a) **COVERAGE.**—Section 1834(l) (42 U.S.C.
5 1395m(l)), as amended by section 426, is amended by
6 adding at the end the following new paragraph:

7 “(11) **ENSURING APPROPRIATE COVERAGE OF**
8 **AIR AMBULANCE SERVICES.**—

9 “(A) **IN GENERAL.**—The regulations de-
10 scribed in section 1861(s)(7) shall ensure that
11 air ambulance services (as defined in subpara-
12 graph (C)) are reimbursed under this sub-
13 section at the air ambulance rate if the air am-
14 bulance service—

15 “(i) is medically necessary based on
16 the health condition of the individual being
17 transported at or immediately prior to the
18 time of the transport; and

19 “(ii) complies with equipment and
20 crew requirements established by the Sec-
21 retary.

22 “(B) **MEDICALLY NECESSARY.**—An air
23 ambulance service shall be considered to be
24 medically necessary for purposes of subpara-
25 graph (A)(i) if such service is requested—

1 “(i) by a physician or a hospital in ac-
2 cordance with the physician’s or hospital’s
3 responsibilities under section 1867 (com-
4 monly known as the Emergency Medical
5 Treatment and Active Labor Act);

6 “(ii) as a result of a protocol estab-
7 lished by a State or regional emergency
8 medical service (EMS) agency;

9 “(iii) by a physician, nurse practi-
10 tioner, physician assistant, registered
11 nurse, or emergency medical responder
12 who reasonably determines or certifies that
13 the patient’s condition is such that the
14 time needed to transport the individual by
15 land or the lack of an appropriate ground
16 ambulance, significantly increases the med-
17 ical risks for the individual; or

18 “(iv) by a Federal or State agency to
19 relocate patients following a natural dis-
20 aster, an act of war, or a terrorist attack.

21 “(C) AIR AMBULANCE SERVICES DE-
22 FINED.—For purposes of this paragraph, the
23 term ‘air ambulance service’ means fixed wing
24 and rotary wing air ambulance services.”.

1 (b) CONFORMING AMENDMENT.—Section 1861(s)(7)
 2 (42 U.S.C. 1395x(s)(7)) is amended by inserting “, sub-
 3 ject to section 1834(l)(11),” after “but”.

4 (c) EFFECTIVE DATE.—The amendments made by
 5 this section shall apply to services furnished on or after
 6 January 1, 2005.

7 **SEC. 427. TREATMENT OF CERTAIN CLINICAL DIAGNOSTIC**
 8 **LABORATORY TESTS FURNISHED BY A SOLE**
 9 **COMMUNITY HOSPITAL.**

10 Notwithstanding subsections (a), (b), and (h) of sec-
 11 tion 1833 of the Social Security Act (42 U.S.C. 1395l)
 12 and section 1834(d)(1) of such Act (42 U.S.C.
 13 1395m(d)(1)), in the case of a clinical diagnostic labora-
 14 tory test covered under part B of title XVIII of such Act
 15 that is furnished in 2005 or 2006 by a sole community
 16 hospital (as defined in section 1886(d)(5)(D)(iii) of such
 17 Act (42 U.S.C. 1395ww(d)(5)(D)(iii))) as part of services
 18 furnished to patients of the hospital, the following rules
 19 shall apply:

20 (1) PAYMENT BASED ON REASONABLE COSTS.—

21 The amount of payment for such test shall be 100
 22 percent of the reasonable costs of the hospital in fur-
 23 nishing such test.

24 (2) NO BENEFICIARY COST-SHARING.—Notwith-
 25 standing section 432, no coinsurance, deductible, co-

1 payment, or other cost-sharing otherwise applicable
 2 under such part B shall apply with respect to such
 3 test.

4 **SEC. 428. IMPROVEMENT IN RURAL HEALTH CLINIC REIM-**
 5 **BURSEMENT.**

6 Section 1833(f) (42 U.S.C. 1395l(f)) is amended—

7 (1) in paragraph (1), by striking “, and” at the
 8 end and inserting a semicolon;

9 (2) in paragraph (2)—

10 (A) by striking “in a subsequent year” and
 11 inserting “in 1989 through 2004”; and

12 (B) by striking the period at the end and
 13 inserting a semicolon; and

14 (3) by adding at the end the following new
 15 paragraphs:

16 “(3) in 2005, at \$80 per visit; and

17 “(4) in a subsequent year, at the limit estab-
 18 lished under this subsection for the previous year in-
 19 creased by the percentage increase in the MEI (as
 20 so defined) applicable to primary care services (as so
 21 defined) furnished as of the first day of that year.”.

1 **SEC. 429. ELIMINATION OF CONSOLIDATED BILLING FOR**
 2 **CERTAIN SERVICES UNDER THE MEDICARE**
 3 **PPS FOR SKILLED NURSING FACILITY SERV-**
 4 **ICES.**

5 (a) CERTAIN RURAL HEALTH CLINIC AND FEDER-
 6 ALLY QUALIFIED HEALTH CENTER SERVICES.—Section
 7 1888(e) (42 U.S.C. 1395yy(e)) is amended—

8 (1) in paragraph (2)(A)(i)(II), by striking
 9 “clauses (ii) and (iii)” and inserting “clauses (ii),
 10 (iii), and (iv)”; and

11 (2) by adding at the end of paragraph (2)(A)
 12 the following new clause:

13 “(iv) EXCLUSION OF CERTAIN RURAL
 14 HEALTH CLINIC AND FEDERALLY QUALI-
 15 FIED HEALTH CENTER SERVICES.—Serv-
 16 ices described in this clause are—

17 “(I) rural health clinic services
 18 (as defined in paragraph (1) of sec-
 19 tion 1861(aa)); and

20 “(II) Federally qualified health
 21 center services (as defined in para-
 22 graph (3) of such section);

23 that would be described in clause (ii) if
 24 such services were furnished by a physician
 25 or practitioner not affiliated with a rural

health clinic or a Federally qualified health center.”.

(b) CERTAIN SERVICES FURNISHED BY AN ENTITY JOINTLY OWNED BY HOSPITALS AND CRITICAL ACCESS HOSPITALS.—For purposes of applying section 411.15(p)–(3)(iii) of title 42 of the Code of Federal Regulations, the Secretary shall treat an entity that is 100 per cent owned as a joint venture by 2 Medicare-participating hospitals or critical access hospitals as a Medicare-participating hospital or a critical access hospital.

(c) TECHNICAL AMENDMENTS.—Sections 1842(b)(6)(E) and 1866(a)(1)(H)(ii) (42 U.S.C. 1395u(b)(6)(E); 1395cc(a)(1)(H)(ii)) are each amended by striking “section 1888(e)(2)(A)(ii)” and inserting “clauses (ii), (iii), and (iv) of section 1888(e)(2)(A)”.

(d) EFFECTIVE DATE.—The amendments made by this section and the provision of subsection (b) shall apply to services furnished on or after January 1, 2005.

SEC. 430. FREEZE IN PAYMENTS FOR CERTAIN ITEMS OF DURABLE MEDICAL EQUIPMENT AND CERTAIN ORTHOTICS; ESTABLISHMENT OF QUALITY STANDARDS AND ACCREDITATION REQUIREMENTS FOR DME PROVIDERS.

(a) FREEZE FOR DME.—Section 1834(a)(14) (42 U.S.C. 1395m(a)(14)) is amended—

1 (1) in subparagraph (E), by striking “and” at
2 the end;

3 (2) in subparagraph (F)—

4 (A) by striking “a subsequent year” and
5 inserting “2003”; and

6 (B) by striking “the previous year.” and
7 inserting “2002;”; and

8 (3) by adding at the end the following new sub-
9 paragraphs:

10 “(G) for each of the years 2004 through
11 2010—

12 “(i) in the case of class III medical
13 devices described in section 513(a)(1)(C)
14 of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 360(c)(1)(C)), the percent-
16 age increase described in subparagraph
17 (B) for the year involved; and

18 “(ii) in the case of covered items not
19 described in clause (i), 0 percentage points;
20 and

21 “(H) for a subsequent year, the percentage
22 increase described in subparagraph (B) for the
23 year involved.”.

(b) FREEZE FOR OFF-THE-SHELF ORTHOTICS.—

Section 1834(h)(4)(A) of the Social Security Act (42 U.S.C. 1395m(h)(4)(A)) is amended—

(1) in clause (vii), by striking “and” at the end;

(2) in clause (viii), by striking “a subsequent year” and inserting “2003”; and

(3) by adding at the end the following new clauses:

“(ix) for each of the years 2004 through 2010—

“(I) in the case of orthotics that have not been custom-fabricated, 0 percent; and

“(II) in the case of prosthetics, prosthetic devices, and custom-fabricated orthotics, the percentage increase described in clause (viii) for the year involved; and

“(x) for 2011 and each subsequent year, the percentage increase described in clause (viii) for the year involved;”.

(c) ESTABLISHMENT OF QUALITY STANDARDS AND ACCREDITATION REQUIREMENTS FOR DURABLE MEDICAL EQUIPMENT PROVIDERS.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended—

1 (1) by redesignating paragraph (17), as added
2 by section 4551(c)(1) of the Balanced Budget Act of
3 1997 (111 Stat. 458), as paragraph (19); and

4 (2) by adding at the end the following new
5 paragraph:

6 “(20) IDENTIFICATION OF QUALITY STAND-
7 ARDS.—

8 “(A) IN GENERAL.—Subject to subpara-
9 graph (C), the Secretary shall establish and im-
10 plement quality standards for providers of dura-
11 ble medical equipment throughout the United
12 States that are developed by recognized inde-
13 pendent accreditation organizations (as des-
14 ignated under subparagraph (B)(i)) and with
15 which such providers shall be required to com-
16 ply in order to—

17 “(i) participate in the program under
18 this title;

19 “(ii) furnish any item or service de-
20 scribed in subparagraph (D) for which
21 payment is made under this part; and

22 “(iii) receive or retain a provider or
23 supplier number used to submit claims for
24 reimbursement for any item or service de-

scribed in subparagraph (D) for which
payment may be made under this title.

“(B) DESIGNATION OF INDEPENDENT AC-
CREDITATION ORGANIZATIONS.—

“(i) IN GENERAL.—Not later than the
date that is 6 months after the date of en-
actment of the Prescription Drug and
Medicare Improvement Act of 2003, the
Secretary shall designate independent ac-
creditation organizations for purposes of
subparagraph (A).

“(ii) CONSULTATION.—In determining
which independent accreditation organiza-
tions to designate under clause (i), the
Secretary shall consult with an expert out-
side advisory panel composed of an appro-
priate selection of representatives of physi-
cians, practitioners, suppliers, and manu-
facturers to review (and advise the Sec-
retary concerning) selection of accrediting
organizations and the quality standards of
such organizations. (A)

“(C) QUALITY STANDARDS.—The quality
standards described in subparagraph (A) may
not be less stringent than the quality standards

1 that would otherwise apply if this paragraph
 2 did not apply and shall include consumer serv-
 3 ices standards.

4 “(D) ITEMS AND SERVICES DESCRIBED.—
 5 The items and services described in this sub-
 6 paragraph are covered items (as defined in
 7 paragraph (13)) for which payment may other-
 8 wise be made under this subsection, other than
 9 items used in infusion, and inhalation drugs
 10 used in conjunction with durable medical equip-
 11 ment.

12 “(E) PHASED-IN IMPLEMENTATION.—The
 13 application of the quality standards described in
 14 subparagraph (A) shall be phased-in over a pe-
 15 riod that does not exceed 3 years.”.

16 **SEC. 431. APPLICATION OF COINSURANCE AND DEDUCT-**
 17 **IBLE FOR CLINICAL DIAGNOSTIC LABORA-**
 18 **TORY TESTS.**

19 (a) COINSURANCE.—

20 (1) IN GENERAL.—Section 1833(a) (42 U.S.C.
 21 1395l(a)) is amended—

22 (A) in paragraph (1)(D)(i), by striking
 23 “(or 100 percent, in the case of such tests for
 24 which payment is made on an assignment-re-
 25 lated basis)”; and

(B) in paragraph (2)(D)(i), by striking “(or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866)”.

(2) CONFORMING AMENDMENT.—The third sentence of section 1866(a)(2)(A) of the Social Security Act (42 U.S.C. 1395cc(a)(2)(A)) is amended by striking “and with respect to clinical diagnostic laboratory tests for which payment is made under part B”.

(b) DEDUCTIBLE.—Section 1833(b) of the Social Security Act (42 U.S.C. 1395l(b)) is amended—

(1) by striking paragraph (3); and

(2) by redesignating paragraphs (4), (5), and (6) as paragraphs (3), (4), and (5), respectively.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2004.

**SEC. 432. BASING MEDICARE PAYMENTS FOR COVERED
OUTPATIENT DRUGS ON MARKET PRICES.**

(a) MEDICARE MARKET BASED PAYMENT AMOUNT.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended—

1 ~~part (1)~~ (1) in paragraph (1), by striking “equal to 95
2 percent of the average wholesale price.” and insert-
3 ing “equal to—

4 “(A) in the case of a drug or biological fur-
5 nished prior to January 1, 2004, 95 percent of the
6 average wholesale price; and

7 “(B) in the case of a drug or biological fur-
8 nished on or after January 1, 2004, the payment
9 amount specified in—

10 “(i) in the case of such a drug or biological
11 that is first available for payment under this
12 ~~part~~ part on or before April 1, 2003, paragraph (4);

13 and

14 “(ii) in the case of such a drug or biologi-
15 cal that is first available for payment under this
16 part after such date, paragraph (5).”; and

17 (2) by adding at the end the following new
18 paragraphs:

19 “(4)(A) Subject to subparagraph (C), the payment
20 amount specified in this paragraph for a year for a drug
21 or biological is an amount equal to the lesser of—

22 “(i) the average wholesale price for the drug or
23 biological; or

24 “(ii) the amount determined under subpara-
25 graph (B)

1 “(B)(i) Subject to clause (ii), the amount determined
2 under this subparagraph is an amount equal to—

3 “(I) in the case of a drug or biological fur-
4 nished in 2004, 85 percent of the average wholesale
5 price for the drug or biological (determined as of
6 April 1, 2003); and

7 “(II) in the case of a drug or biological fur-
8 nished in 2005 or a subsequent year, the amount de-
9 termined under this subparagraph for the previous
10 year increased by the percentage increase in the con-
11 sumer price index for medical care for the 12-month
12 period ending with June of the previous year.

13 “(ii) In the case of a vaccine described in subpara-
14 graph (A) or (B) of section 1861(s)(10), the amount de-
15 termined under this subparagraph is an amount equal to
16 the average wholesale price for the drug or biological.

17 “(C)(i) The Secretary shall establish a process under
18 which the Secretary determines, for such drugs or
19 biologicals as the Secretary determines appropriate,
20 whether the widely available market price to physicians or
21 suppliers for the drug or biological furnished in a year
22 is different from the payment amount established under
23 subparagraph (B) for the year. Such determination shall
24 be based on the information described in clause (ii) as the
25 Secretary determines appropriate.

1 (ii) The information described in this clause is the
2 following information:

“(1) Any report on drug or biological market prices by the Inspector General of the Department of Health and Human Services or the Comptroller General of the United States that is made available after December 31, 1999.

“(II) A review of drug or biological market prices by the Secretary, which may include information on such market prices from insurers, private health plans, manufacturers, wholesalers, distributors, physician supply houses, specialty pharmacies, group purchasing arrangements, physicians, suppliers, or any other source the Secretary determines appropriate.

“(III) Data and information submitted by the
manufacturer of the drug or biological or by another
entity.

19 “(IV) Other data and information as deter-
20 mined appropriate by the Secretary.

21 “(iii) If the Secretary makes a determination under
22 clause (i) with respect to the widely available market price
23 for a drug or biological for a year, the following provisions
24 shall apply:

1 “(I) Subject to clause (iv), the amount deter-
2 mined under this subparagraph shall be substituted
3 for the amount determined under subparagraph (B)
4 for purposes of applying subparagraph (A)(ii)(I) for
5 the year and all subsequent years.

6 “(II) The Secretary may make subsequent de-
7 terminations under clause (i) with respect to the
8 widely available market price for the drug or biologi-
9 cal.

10 “(III) If the Secretary does not make a subse-
11 quent determination under clause (i) with respect to
12 the widely available market price for the drug or bio-
13 logical for a year, the amount determined under this
14 subparagraph shall be an amount equal to the
15 amount determined under this subparagraph for the
16 previous year increased by the percentage increase
17 described in subparagraph (B)(i)(II) for the year in-
18 volved.

19 “(iv) If the first determination made under clause (i)
20 with respect to the widely available market price for a
21 drug or biological would result in a payment amount in
22 a year that is more than 15 percent less than the amount
23 determined under subparagraph (B) for the drug or bio-
24 logical for the previous year (or, for 2004, the payment
25 amount determined under paragraph (1)(A), determined

1 as of April 1, 2003), the Secretary shall provide for a tran-
2 sition to the amount determined under clause (i) so that
3 the payment amount is reduced in annual increments
4 equal to 15 percent of the payment amount in such pre-
5 vious year until the payment amount is equal to the
6 amount determined under clause (i), as increased each
7 year by the percentage increase described in subparagraph
8 (B)(i)(II) for the year. The preceding sentence shall not
9 apply to a drug or biological where a generic version of
10 the drug or biological first enters the market on or after
11 January 1, 2004 (even if the generic version of the drug
12 or biological is not marketed under the chemical name of
13 such drug or biological).

14 “(5) In the case of a drug or biological that is first
15 available for payment under this part after April 1, 2003,
16 the following rules shall apply:

17 “(A) As a condition of obtaining a code to re-
18 port such new drug or biological and to receive pay-
19 ment under this part, a manufacturer shall provide
20 the Secretary (in a time, manner, and form ap-
21 proved by the Secretary) with data and information
22 on prices at which the manufacturer estimates phy-
23 sicians and suppliers will be able to routinely obtain
24 the drug or biological in the market during the first
25 year that the drug or biological is available for pay-

1 ment under this part and such additional informa-
2 tion that the manufacturer determines appropriate.

3 “(B) During the year that the drug or biologi-
4 cal is first available for payment under this part, the
5 manufacturer of the drug or biological shall provide
6 the Secretary (in a time, manner, and form ap-
7 proved by the Secretary) with updated information
8 on the actual market prices paid by such physicians
9 or suppliers for the drug or biological in the year.

10 “(C) The amount specified in this paragraph
11 for a drug or biological for the year described in
12 subparagraph (B) is equal to an amount determined
13 by the Secretary based on the information provided
14 under subparagraph (A) and other information that
15 the Secretary determines appropriate.

16 “(D) The amount specified in this paragraph
17 for a drug or biological for the year after the year
18 described in subparagraph (B) is equal to an
19 amount determined by the Secretary based on the
20 information provided under subparagraph (B) and
21 other information that the Secretary determines ap-
22 propriate.

23 “(E) The amount specified in this paragraph
24 for a drug or biological for the year beginning after

1 the year described in subparagraph (D) and each
2 subsequent year is equal to the lesser of—

3 “(i) the average wholesale price for the
4 drug or biological; or
5 “(ii) the amount determined—

6 “(I) by the Secretary under paragraph
7 (4)(C)(i) with respect to the widely avail-
8 able market price for the drug or biological
9 for the year, if such paragraph was applied
10 by substituting ‘the payment determined
11 under paragraph (5)(E)(ii)(II) for the
12 year’ for ‘established under subparagraph
13 (B) for the year’; and

14 “(II) if no determination described in
15 subclause (I) is made for the drug or bio-
16 logical for the year, under this subpara-
17 graph with respect to the drug or biological
18 for the previous year increased by the per-
19 centage increase described in paragraph
20 (4)(B)(i)(II) for the year involved.”.

21 (b) ADJUSTMENTS TO PAYMENT AMOUNTS FOR AD-
22 MINISTRATION OF DRUGS AND BIOLOGICALS.—

23 (1) ADJUSTMENT IN PHYSICIAN PRACTICE EX-
24 PENSE RELATIVE VALUE UNITS.—Section
25 1848(c)(2) (42 U.S.C. 1395w-4(c)(2)) is amended—

1 (A) in subparagraph (B)—

2 (i) in clause (ii)(II), by striking “The
3 ~~adjustments~~ adjustments” and inserting “Subject to
4 clause (iv), the adjustments”; and

5 (ii) by adding at the end the following
6 new clause:

7 “(iv) EXEMPTION FROM BUDGET
8 NEUTRALITY IN 2004.—Any additional ex-
9 penditures under this part that are attrib-
10 utable to subparagraph (H) shall not be
11 taken into account in applying clause
12 (ii)(II) for 2004.”; and

13 (B) by adding at the end the following new
14 subparagraph:

15 “(H) ADJUSTMENTS IN PRACTICE EX-
16 PENSE RELATIVE VALUE UNITS FOR DRUG AD-
17 MINISTRATION SERVICES FOR 2004.—In estab-
18 lishing the physician fee schedule under sub-
19 section (b) with respect to payments for services
20 furnished in 2004, the Secretary shall, in deter-
21 mining practice expense relative value units
22 under this subsection, utilize a survey sub-
23 mitted to the Secretary as of January 1, 2003,
24 by a physician specialty organization pursuant
25 to section 212 of the Medicare, Medicaid, and

1 SCHIP Balanced Budget Refinement Act of
2 1999 if the survey—

3 “(i) covers practice expenses for on-
4 tology administration services; and

5 “(ii) meets criteria established by the
6 Secretary for acceptance of such surveys.”.

7 (2) PAYMENT FOR MULTIPLE CHEMOTHERAPY
8 AGENTS FURNISHED ON A SINGLE DAY THROUGH
9 THE PUSH TECHNIQUE.—

10 (A) REVIEW OF POLICY.—The Secretary
11 shall review the policy, as in effect on the date
12 of enactment of this Act, with respect to pay-
13 ment under section 1848 of the Social Security
14 Act (42 U.S.C. 1395w-4) for the administra-
15 tion of more than 1 anticancer
16 chemotherapeutic agent to an individual on a
17 single day through the push technique.

18 (B) MODIFICATION OF POLICY.—After
19 conducting the review under subparagraph (A),
20 the Secretary shall modify such payment policy
21 if the Secretary determines such modification to
22 be appropriate.

23 (C) EXEMPTION FROM BUDGET NEU-
24 TRALITY UNDER PHYSICIAN FEE SCHEDULE.—

25 If the Secretary modifies such payment policy

pursuant to subparagraph (B), any increased expenditures under title XVIII of the Social Security Act resulting from such modification shall be treated as additional expenditures attributable to subparagraph (H) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w-4(c)(2)), as added by paragraph (1)(B), for purposes of applying the exemption to budget neutrality under subparagraph (B)(iv) of such section, as added by paragraph (1)(A).

(3) TREATMENT OF OTHER SERVICES CURRENTLY IN THE NONPHYSICIAN WORK POOL.—The Secretary shall make adjustments to the nonphysician work pool methodology (as such term is used in the final rule promulgated by the Secretary in the Federal Register on December 31, 2002 (67 Fed. Reg. 251)), for the determination of practice expense relative value units under the physician fee schedule under section 1848(c)(2)(C)(ii) of the Social Security Act (42 U.S.C. 1395w-4(c)(2)(C)(ii)), so that the practice expense relative value units for services determined under such methodology are not disproportionately reduced relative to the practice expense relative value units of services not deter-

1 mined under such methodology, as a result of the
2 amendments to such Act made by paragraph (1).

3 (4) ADMINISTRATION OF BLOOD CLOTTING FAC-
4 TORS.—Section 1842(o) (42 U.S.C. 1395u(o)), as
5 amended by subsection (a)(2), is amended by adding
6 at the end the following new paragraph:

7 “(6)(A) Subject to subparagraph (B), in the case of
8 clotting factors furnished on or after January 1, 2004,
9 the Secretary shall, after reviewing the January 2003 re-
10 port to Congress by the Comptroller General of the United
11 States entitled ‘Payment for Blood Clotting Factor Ex-
12 ceeds Providers Acquisition Cost’ (GAO–03–184), provide
13 for a separate payment for the administration of such
14 blood clotting factors in an amount that the Secretary de-
15 termines to be appropriate.

16 “(B) In determining the separate payment amount
17 under subparagraph (A) for blood clotting factors fur-
18 nished in 2004, the Secretary shall ensure that the total
19 amount of payments under this part (as estimated by the
20 Secretary) for such factors under paragraphs (4) and (5)
21 and such separate payments for such factors does not ex-
22 ceed the total amount of payments that would have been
23 made for such factors under this part (as estimated by
24 the Secretary) if the amendments made by section 433

1 of the Prescription Drug and Medicare Improvement Act
2 of 2003 had not been enacted.

3 “(C) The separate payment amount under this sub-
4 paragraph for blood clotting factors furnished in 2005 or
5 a subsequent year shall be equal to the separate payment
6 amount determined under this paragraph for the previous
7 year increased by the percentage increase described in
8 paragraph (4)(B)(i)(II) for the year involved.”.

9 (5) INCREASE IN COMPOSITE RATE FOR END
10 STAGE RENAL DISEASE FACILITIES.—Section
11 1881(b) (42 U.S.C. 1395rr(b) is amended—

12 (A) in paragraph (7), by adding at the end
13 the following new sentence: “In the case of di-
14 alysis services furnished in 2004 or a subse-
15 quent year, the composite rate for such services
16 shall be determined under paragraph (12).”;
17 and

18 (B) by adding at the end the following new
19 paragraph:

20 “(12)(A) In the case of dialysis services furnished
21 during 2004, the composite rate for such services shall be
22 the composite rate that would otherwise apply under para-
23 graph (7) for the year increased by an amount to ensure
24 (as estimated by the Secretary) that—

25 “(i) the sum of the total amount of—

1 “(I) the composite rate payments for such
 2 services for the year, as increased under this
 3 paragraph; and

4 “(II) the payments for drugs and
 5 biologicals (other than erythropoetin) furnished
 6 in connection with the furnishing of renal dialy-
 7 sis services and separately billed by renal dialy-
 8 sis facilities under paragraphs (4) and (5) of
 9 section 1842(o) for the year; is equal to

10 “(ii) the sum of the total amount of the com-
 11 posite rate payments under paragraph (7) for the
 12 year and the payments for the separately billed
 13 drugs and biologicals described in clause (i)(II) that
 14 would have been made if the amendments made by
 15 section 433 of the Prescription Drug and Medicare
 16 Improvement Act of 2003 had not been enacted.

17 “(B) Subject to subparagraph (E), in the case of di-
 18 alysis services furnished in 2005, the composite rate for
 19 such services shall be an amount equal to the composite
 20 rate established under subparagraph (A), increased by
 21 0.05 percent and further increased by 1.6 percent.

22 “(C) Subject to subparagraph (E), in the case of di-
 23 alysis services furnished in 2006, the composite rate for
 24 such services shall be an amount equal to the composite

1 rate established under subparagraph (B), increased by
2 0.05 percent and further increased by 1.6 percent.

3 “(D) Subject to subparagraph (E), in the case of di-
4 alysis services furnished in 2007 and all subsequent years,
5 the composite rate for such services shall be an amount
6 equal to the composite rate established under this para-
7 graph for the previous year, increased by 0.05 percent.

8 “(E) If the Secretary implements a reduction in the
9 payment amount under paragraph (4)(C) or (5) for a drug
10 or biological described in subparagraph (A)(i)(II) for a
11 year after 2004, the Secretary shall, as estimated by the
12 Secretary—

13 “(i) increase the composite rate for dialysis
14 services furnished in such year in the same manner
15 that the composite rate for such services for 2004
16 was increased under subparagraph (A); and

17 “(ii) increase the percentage increase under
18 subparagraph (C) or (D) (as applicable) for years
19 after the year described in clause (i) to ensure that
20 such increased percentage would result in expendi-
21 tures equal to the sum of the total composite rate
22 payments for such services for such years and the
23 total payments for drugs and biologicals described in
24 subparagraph (A)(i)(II) is equal to the sum of the
25 total amount of the composite rate payments under

1 this paragraph for such years and the payments for
 2 the drugs and biologicals described in subparagraph
 3 (A)(i)(II) that would have been made if the reduc-
 4 tion in payment amount described in subparagraph
 5 had not been made.

6 “(F) There shall be no administrative or judicial re-
 7 view under section 1869, section 1878, or otherwise, of
 8 determinations of payment amounts, methods, or adjust-
 9 ments under this paragraph.”.

10 (6) HOME INFUSION DRUGS.—Section 1842(o)
 11 (42 U.S.C. 1395u(o)), as amended by subsection
 12 (a)(2) and paragraph (4), is amended by adding at
 13 the end the following new paragraph:

14 “(7)(A) Subject to subparagraph (B), in the case of
 15 infusion drugs and biologicals furnished through an item
 16 of durable medical equipment covered under section
 17 1861(n) on or after January 1, 2004, the Secretary may
 18 make separate payments for furnishing such drugs and
 19 biologicals in an amount determined by the Secretary if
 20 the Secretary determines such separate payment to be ap-
 21 propriate.

22 “(B) In determining the amount of any separate pay-
 23 ment under subparagraph (A) for a year, the Secretary
 24 shall ensure that the total amount of payments under this
 25 part for such infusion drugs and biologicals for the year

1 and such separate payments for the year does not exceed
2 the total amount of payments that would have been made
3 under this part for the year for such infusion drugs and
4 biologicals if section 433 of the Prescription Drug and
5 Medicare Improvement Act of 2003 had not been en-
6 acted.”.

7 (7) INHALATION DRUGS.—Section 1842(o) (42
8 U.S.C. 1395u(o)), as amended by subsection (a)(2)
9 and paragraphs (4) and (6), is amended by adding
10 at the end the following new paragraph:

11 “(8)(A) Subject to subparagraph (B), in the case of
12 inhalation drugs and biologicals furnished through durable
13 medical equipment covered under section 1861(n) on or
14 after January 1, 2004, the Secretary may increase pay-
15 ments for such equipment under section 1834(a) and may
16 make separate payments for furnishing such drugs and
17 biologicals if the Secretary determines such increased or
18 separate payments are necessary to appropriately furnish
19 such equipment and drugs and biologicals to beneficiaries.

20 “(B) The total amount of any increased payments
21 and separate payments under subparagraph (A) for a year
22 may not exceed an amount equal to 10 percent of the
23 amount (as estimated by the Secretary) by which—

24 “(i) the total amount of payments that would
25 have been made for such drugs and biologicals for

1 the year if section 433 of the Prescription Drug and
 2 Medicare Improvement Act of 2003 had not been en-
 3 acted; exceeds

4 “(ii) the total amount of payments for such
 5 drugs and biologicals under paragraphs (4) and
 6 (5).”.

7 (8) PHARMACY DISPENSING FEE FOR CERTAIN
 8 DRUGS AND BIOLOGICALS.—Section 1842(o)(2) (42
 9 U.S.C. 1395u(o)(2)) is amended to read as follows:
 10 “(2) If payment for a drug or biological is made to
 11 a licensed pharmacy approved to dispense drugs or
 12 biologicals under this part, the Secretary—

13 “(A) in the case of an immunosuppressive drug
 14 described in subparagraph (J) of section 1861(s)(2)
 15 and an oral drug described in subparagraph (Q) or
 16 (T) of such section, shall pay a dispensing fee deter-
 17 mined appropriate by the Secretary (less the applica-
 18 ble deductible and coinsurance amounts) to the
 19 pharmacy; and

20 “(B) in the case of a drug or biological not de-
 21 scribed in subparagraph (A), may pay a dispensing
 22 fee determined appropriate by the Secretary (less
 23 the applicable deductible and coinsurance amounts)
 24 to the pharmacy.”.

1 (9) PAYMENT FOR CHEMOTHERAPY DRUGS
2 PURCHASED BUT NOT ADMINISTERED BY PHYSI-
3 CIANS.—Section 1842(o) (42 U.S.C. 1395u(o)), as
4 amended by subsection (a)(2) and paragraphs (4),
5 (6) and (7), is amended by adding at the end the
6 following new paragraph:

7 “(9)(A) Subject to subparagraph (B), the Sec-
8 retary may increase (in an amount determined ap-
9 propriate) the amount of payments to physicians for
10 anticancer chemotherapeutic drugs or biologicals
11 that would otherwise be made under this part in
12 order to compensate such physicians for anticancer
13 chemotherapeutic drugs or biologicals that are pur-
14 chased by physicians with a reasonable intent to ad-
15 minister to an individual enrolled under this part
16 but which cannot be administered to such individual
17 despite the reasonable efforts of the physician.

18 “(B) The total amount of increased payments
19 made under subparagraph (A) in a year (as esti-
20 mated by the Secretary) may not exceed an amount
21 equal to 1 percent of the total amount of payments
22 made under paragraphs (4) and (5) for such
23 anticancer chemotherapeutic drugs or biologicals fur-
24 nished by physicians in such year (as estimated by
25 the Secretary).”.

1 (c) LINKAGE OF REVISED DRUG PAYMENTS AND IN-
 2 CREASES FOR DRUG ADMINISTRATION.—The Secretary
 3 shall not implement the revisions in payment amounts for
 4 a category of drug or biological as a result of the amend-
 5 ments made by subsection (a) unless the Secretary concur-
 6 rently implements the adjustments to payment amounts
 7 for administration of such category of drug or biological
 8 for which the Secretary is required to make an adjust-
 9 ment, as specified in the amendments made by, and provi-
 10 sions of, subsection (b).

11 (d) PROHIBITION OF ADMINISTRATIVE AND JUDI-
 12 CIAL REVIEW.—

13 (1) DRUGS.—Section 1842(o) (42 U.S.C.
 14 1395u(o)), as amended by subsection (a)(2) and
 15 paragraphs (4), (6), (7), and (9) of subsection (b),
 16 is amended by adding at the end the following new
 17 paragraph:

18 “(10) There shall be no administrative or judicial re-
 19 view under section 1869, section 1878, or otherwise, of
 20 determinations of payment amounts, methods, or adjust-
 21 ments under paragraph (2) or paragraphs (4) through
 22 (9).”.

23 (2) PHYSICIAN FEE SCHEDULE.—Section
 24 1848(i)(1) (42 U.S.C. 1395w-4(i)(1)) is amended—

(A) in subparagraph (D), by striking
“and” at the end;

(B) in subparagraph (E), by striking the
period at the end and inserting “, and”; and

(C) by adding at the end the following new
subparagraph:

“(F) adjustments in practice expense rel-
ative value units under subsection (c)(2)(H).”.

(3) MULTIPLE CHEMOTHERAPY AGENTS AND
OTHER SERVICES CURRENTLY ON THE NON-PHYSI-
CIAN WORK POOL.—There shall be no administrative
or judicial review under section 1869, section 1878,
or otherwise, of determinations of payment amounts,
methods, or adjustments under paragraphs (2) and
(3) of subsection (b).

(e) STUDIES AND REPORTS.—

(1) GAO STUDY AND REPORT ON BENEFICIARY
ACCESS TO DRUGS AND BIOLOGICALS.—

(A) STUDY.—The Comptroller General of
the United States shall conduct a study that ex-
amines the impact the provisions of, and the
amendments made by, this section have on ac-
cess by medicare beneficiaries to drugs and
biologicals covered under the medicare program.

1 (B) REPORT.—Not later than January 1,
 2 2006, the Comptroller General shall submit a
 3 report to Congress on the study conducted
 4 under subparagraph (A) together with such rec-
 5 ommendations as the Comptroller General de-
 6 termines to be appropriate.

7 (2) STUDY AND REPORT BY THE HHS INSPEC-
 8 TOR GENERAL ON MARKET PRICES OF DRUGS AND
 9 BIOLOGICALS.—

10 (A) STUDY.—The Inspector General of the
 11 Department of Health and Human Services
 12 shall conduct 1 or more studies that—

13 (i) examine the market prices that
 14 drugs and biologicals covered under the
 15 medicare program are widely available to
 16 physicians and suppliers; and

17 (ii) compare such widely available
 18 market prices to the payment amount for
 19 such drugs and biologicals under section
 20 1842(o) of the Social Security Act (42
 21 U.S.C. 1395u(o)).

22 (B) REQUIREMENT.—In conducting the
 23 study under subparagraph (A), the Inspector
 24 General shall focus on those drugs and
 25 biologicals that represent the largest portions of

expenditures under the medicare program for
drugs and biologicals.

(C) REPORT.—The Inspector General shall
prepare a report on any study conducted under
subparagraph (A).

SEC. 433. INDEXING PART B DEDUCTIBLE TO INFLATION.

The first sentence of section 1833(b) (42 U.S.C.
1395l(b)) is amended by striking “and \$100 for 1991 and
subsequent years” and inserting the following: “, \$100 for
1991 through 2005, \$125 for 2006, and for 2007 and
thereafter, the amount in effect for the previous year, in-
crease by the percentage increase in the consumer price
index for all urban consumers (U.S. city average) for the
12-month period ending with June of the previous year,
rounded to the nearest dollar”.

SEC. 434. REVISIONS TO REASSIGNMENT PROVISIONS.

(a) IN GENERAL.—Section 1842(b)(6)(A)(ii) (42
U.S.C. 1395u(b)(6)(A)(ii)) is amended to read as follows:
“(ii) where the service was provided under a contractual
arrangement between such physician or other person and
an entity (as defined by the Secretary), to the entity if
under such arrangement such entity submits the bill for
such service and such arrangement meets such program
integrity and other safeguards as the Secretary may deter-
mine to be appropriate.”.

(b) CONFORMING AMENDMENT.—The second sentence of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended by striking “except to an employer or facility as described in clause (A)” and inserting “except to an employer or entity as described in subparagraph (A)”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to payments made on or after the date of enactment of this Act.

SEC. 435. EXTENSION OF TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES UNDER MEDICAL CARE.

Section 542(c) of BIPA (114 Stat. 2763A–551) is amended by inserting “, and for services furnished during 2005” before the period at the end.

SEC. 436. ADEQUATE REIMBURSEMENT FOR OUTPATIENT PHARMACY THERAPY UNDER THE HOSPITAL OUTPATIENT PPS.

(a) SPECIAL RULES FOR DRUGS AND BIOLOGICALS.—Section 1833(t) (42 U.S.C. 1395(t)) is amended—

(1) by redesignating paragraph (13) as paragraph (14); and

(2) by inserting after paragraph (12) the following new paragraph:

1 “(13) SPECIAL RULES FOR CERTAIN DRUGS
2 AND BIOLOGICALS.—

3 “(A) BEFORE 2007.—

4 “(i) IN GENERAL.—Notwithstanding
5 paragraph (6), but subject to clause (ii),
6 with respect to a separately payable drug
7 or biological described in subparagraph
8 (D) furnished on or after January 1, 2005,
9 and before January 1, 2007, hospitals
10 shall be reimbursed as follows:

11 “(I) DRUGS AND BIOLOGICALS

12 FURNISHED AS PART OF A CURRENT

13 OPD SERVICE.—The amount of pay-

14 ment for a drug or biological de-

15 scribed in subparagraph (D) provided

16 as a part of a service that was a cov-

17 ered OPD service on May 1, 2003,

18 shall be the applicable percentage (as

19 defined in subparagraph (C)) of the

20 average wholesale price for the drug

21 or biological that would have been de-

22 termined under section 1842(o) on

23 such date.

24 “(II) DRUGS AND BIOLOGICALS

25 FURNISHED AS PART OF OTHER OPD

1 SERVICES.—The amount of payment
 2 for a drug or biological described in
 3 subparagraph (D) provided as part of
 4 any other covered OPD service shall
 5 be the applicable percentage (as de-
 6 fined in subparagraph (C)) of the av-
 7 erage wholesale price that would have
 8 been determined under section
 9 1842(o) on May 1, 2003, if payment
 10 for such a drug or biological could
 11 have been made under this part on
 12 that date.

13 “(ii) UPDATE FOR 2006.—For 2006,
 14 the amounts determined under clauses (i)
 15 and (ii) shall be the amount established for
 16 2005 increased by the percentage increase
 17 in the Consumer Price Index for all urban
 18 consumers (U.S. urban average) for the
 19 12-month period ending with June of the
 20 previous year.

21 “(B) AFTER 2007.—

22 “(i) ONGOING STUDY AND REPORTS
 23 ON ADEQUATE REIMBURSEMENTS.—

24 “(I) STUDY.—The Secretary
 25 shall contract with an eligible organi-

for acquisition (as defined in subclause (IV))
 to conduct a study to determine the
 of mean hospital acquisition, pharmacy serv-
 ices, and handling costs for each indi-
 vidual drug or biological described in
 subparagraph (D).

“(II) STUDY REQUIREMENTS.—

The study conducted under subclause
 (I) shall—

“(aa) be accurate to within
 3 percent of true mean hospital
 — acquisition and handling costs for
 each drug and biological at the
 95 percent confidence level;

“(bb) begin not later than
 January 1, 2005; and

“(cc) be updated annually
 for changes in hospital costs and
 the addition of newly marketed
 products.

“(III) REPORTS.—Not later than
 January 1 of each year (beginning
 with 2006), the Secretary shall submit
 to Congress a report on the study
 conducted under clause (i) together

1 with recommendations for such legis-
2 lative or administrative action as the
3 Secretary determines to be appro-
4 priate.

5 “(IV) ELIGIBLE ORGANIZATION
6 DEFINED.—In this clause, the term
7 ‘eligible organization’ means a private,
8 nonprofit organization within the
9 meaning of section 501(c) of the In-
10 ternal Revenue Code.

11 “(ii) ESTABLISHMENT OF PAYMENT
12 METHODOLOGY.—Notwithstanding para-
13 graph (6), the Secretary, in establishing a
14 payment methodology on or after the date
15 of enactment of the Prescription Drug and
16 Medicare Improvement Act of 2003, shall
17 take into consideration the findings of the
18 study conducted under clause (i)(I) in de-
19 termining payment amounts for each drug
20 and biological provided as part of a covered
21 OPD service furnished on or after January
22 1, 2007.

23 “(C) APPLICABLE PERCENTAGE DE-
24 FINED.—In this paragraph, the term ‘applicable
25 percentage’ means—

1 “(i) with respect to a biological prod-
2 uct (approved under a biologics license ap-
3 plication under section 351 of the Public
4 Health Service Act), a single source drug
5 (as defined in section 1927(k)(7)(A)(iv)),
6 or an orphan product designated under
7 section 526 of the Food, Drug, and Cos-
8 metic Act to which the prospective pay-
9 ment system established under this sub-
10 section did not apply under the final rule
11 for 2003 payments under such system, 94
12 percent; [offered/estimated at 91 percent]

13 “(ii) with respect to an innovator mul-
14 tiple source drug (as defined in section
15 1927(k)(7)(A)(ii)), 91 percent; and [offered/

16 “(iii) with respect to a noninnovator
17 multiple source drug (as defined in as de-
18 fined in section 1927(k)(7)(A)(iii)), 71 per-
19 cent. [offered/estimated at 71 percent]

20 “(D) DRUGS AND BIOLOGICALS DE-
21 SCRIBED.—A drug or biological described in
22 this paragraph is any drug or biological—

23 “(i) for which the amount of payment
24 was determined under paragraph (6) prior
25 to January 1, 2005; and

1 “(ii)(I) which is assigned to a drug
 2 specific ambulatory payment classification
 3 on or after the date of enactment of the
 4 Prescription Drug and Medicare Improve-
 5 ment Act of 2003; or

6 “(II) that would have been reimbursed
 7 under paragraph (6) but for the applica-
 8 tion of this paragraph.”.

9 (b) EXCEPTIONS TO BUDGET NEUTRALITY REQUIRE-
 10 MENT.—Section 1833(t)(9)(B) (42 U.S.C.
 11 1395l(t)(9)(B)) is amended by adding at the end the fol-
 12 lowing: “In determining the budget neutrality adjustment
 13 required by the preceding sentence for fiscal years 2005
 14 and 2006, the Secretary shall not take into account any
 15 expenditures that would not have been made but for the
 16 application of paragraph (13).”.

17 **SEC. 437. LIMITATION OF APPLICATION OF FUNCTIONAL**
 18 **EQUIVALENCE STANDARD.**

19 Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amend-
 20 ed by adding at the end the following new subparagraph:

21 “(F) LIMITATION OF APPLICATION OF
 22 FUNCTIONAL EQUIVALENCE STANDARD.—

23 “(i) IN GENERAL.—The Secretary
 24 may not publish regulations that apply a

functional equivalence standard to a drug or biological under this paragraph.

“(ii) APPLICATION.—Paragraph (1) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Prescription Drug and Medicare Improvement Act of 2003 unless—

“(I) such application was being made to such drug or biological prior to such date of enactment; and

“(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

“(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to effect the Secretary’s authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent,

1 as determined by the Commissioner of
2 Food and Drugs.

3 **SEC. 438. MEDICARE COVERAGE OF ROUTINE COSTS ASSO-**
4 **CIATED WITH CERTAIN CLINICAL TRIALS.**

5 (a) IN GENERAL.—With respect to the coverage of
6 routine costs of care for beneficiaries participating in a
7 qualifying clinical trial, as set forth on the date of the en-
8 actment of this Act in National Coverage Determination
9 30–1 of the Medicare Coverage Issues Manual, the Sec-
10 retary shall deem clinical trials conducted in accordance
11 with an investigational device exemption approved under
12 section 520(g) of the Federal Food, Drug, and Cosmetic
13 Act (42 U.S.C. 360j(g)) to be automatically qualified for
14 such coverage.

15 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
16 tion shall be construed as authorizing or requiring the Sec-
17 retary to modify the regulations set forth on the date of
18 the enactment of this Act at subpart B of part 405 of
19 title 42, Code of Federal Regulations, or subpart A of part
20 411 of such title, relating to coverage of, and payment
21 for, a medical device that is the subject of an investiga-
22 tional device exemption by the Food and Drug Adminis-
23 tration (except as may be necessary to implement sub-
24 section (a)).

1 (c) LIMITATION OF EXPENDITURES IN YEARS PRIOR
2 TO 2014.—

3 (1) IN GENERAL.—The Secretary shall ensure
4 that the total amount of expenditures under title
5 XVIII of the Social Security Act (including amounts
6 expended by reason of this section) in a year prior
7 to 2014 does not exceed the sum of—

8 (A) the total amount of expenditures under
9 such title XVIII that would have made if this
10 section had not been enacted; and

11 (B) the applicable amount.

12 (2) APPLICABLE AMOUNT.—For purposes of
13 paragraph (1), the term “applicable amount”
14 means—

15 (A) for 2005, \$32,000,000;

16 (B) for 2006, \$34,000,000;

17 (C) for 2007, \$36,000,000;

18 (D) for 2008, \$38,000,000;

19 (E) for 2009, \$40,000,000;

20 (F) for 2010, \$42,000,000;

21 (G) for 2011, \$44,000,000;

22 (H) for 2012, \$48,000,000; and

23 (I) for 2013, \$50,000,000.

24 (3) STEPS TO ENSURE FUNDING LIMITATION
25 NOT VIOLATED.—If the Secretary determines that

1 the application of this section will result in the fund-
 2 ing limitation described in paragraph (1) being vio-
 3 lated for any year, the Secretary shall take appro-
 4 priate steps to stay within such funding limitation,
 5 including through limiting the number of clinical
 6 trials deemed under subsection (a) and only covering
 7 a portion of the routine costs described in such sub-
 8 section.

9 (d) EFFECTIVE DATE.—This section shall apply to
 10 clinical trials begun on or after January 1, 2005.

11 **SEC. 439. WAIVER OF PART B LATE ENROLLMENT PENALTY**
 12 **FOR CERTAIN MILITARY RETIREES; SPECIAL**
 13 **ENROLLMENT PERIOD.**

14 (a) WAIVER OF PENALTY.—

15 (1) IN GENERAL.—Section 1839(b) (42 U.S.C.
 16 1395r(b)) is amended by adding at the end the fol-
 17 lowing new sentence: “No increase in the premium
 18 shall be effected for a month in the case of an indi-
 19 vidual who is 65 years of age or older, who enrolls
 20 under this part during 2002, 2003, 2004, or 2005
 21 and who demonstrates to the Secretary before De-
 22 cember 31, 2005, that the individual is a covered
 23 beneficiary (as defined in section 1072(5) of title 10,
 24 United States Code). The Secretary shall consult

with the Secretary of Defense in identifying individuals described in the previous sentence.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to premiums for months beginning with January 2005. The Secretary shall establish a method for providing rebates of premium penalties paid for months on or after January 2005 for which a penalty does not apply under such amendment but for which a penalty was previously collected.

(b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

(1) IN GENERAL.—In the case of any individual who, as of the date of enactment of this Act, is 65 years of age or older, is eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act, and is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code), the Secretary shall provide for a special enrollment period during which the individual may enroll under such part. Such period shall begin 1 year after the date of the enactment of this Act and shall end on December 31, 2005.

(2) COVERAGE PERIOD.—In the case of an individual who enrolls during the special enrollment pe-

1 riod provided under paragraph (1), the coverage pe-
 2 riod under part B of title XVIII of the Social Secu-
 3 rity Act shall begin on the first day of the month
 4 following the month in which the individual enrolls.

5 **SEC. 440. DEMONSTRATION OF COVERAGE OF CHIRO-**
 6 **PRACTIC SERVICES UNDER MEDICARE.**

7 (a) DEFINITIONS.—In this section:

8 (1) CHIROPRACTIC SERVICES.—The term
 9 “chiropractic services” has the meaning given that
 10 term by the Secretary for purposes of the dem-
 11 onstration projects, but shall include, at a min-
 12 imum—

13 (A) care for neuromusculoskeletal condi-
 14 tions typical among eligible beneficiaries; and

15 (B) diagnostic and other services that a
 16 chiropractor is legally authorized to perform by
 17 the State or jurisdiction in which such treat-
 18 ment is provided.

19 (2) DEMONSTRATION PROJECT.—The term
 20 “demonstration project” means a demonstration
 21 project established by the Secretary under sub-
 22 section (b)(1).

23 (3) ELIGIBLE BENEFICIARY.—The term “eligi-
 24 ble beneficiary” means an individual who is enrolled
 25 under part B of the medicare program.

(4) MEDICARE PROGRAM.—The term “medicare program” means the health benefits program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(b) DEMONSTRATION OF COVERAGE OF CHIROPRACTIC SERVICES UNDER MEDICARE.—

(1) ESTABLISHMENT.—The Secretary shall establish demonstration projects in accordance with the provisions of this section for the purpose of evaluating the feasibility and advisability of covering chiropractic services under the medicare program (in addition to the coverage provided for services consisting of treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Social Security Act (42 U.S.C. 1395x(r)(5))).

(2) NO PHYSICIAN APPROVAL REQUIRED.—In establishing the demonstration projects, the Secretary shall ensure that an eligible beneficiary who participates in a demonstration project, including an eligible beneficiary who is enrolled for coverage under a Medicare+Choice plan (or, on and after January 1, 2006, under a MedicareAdvantage plan), is not required to receive approval from a physician

1 or other health care provider in order to receive a
2 chiropractic service under a demonstration project.

3 (3) CONSULTATION.—In establishing the dem-
4 onstration projects, the Secretary shall consult with
5 chiropractors, organizations representing chiroprac-
6 tors, eligible beneficiaries, and organizations rep-
7 resenting eligible beneficiaries.

8 (4) PARTICIPATION.—Any eligible beneficiary
9 may participate in the demonstration projects on a
10 voluntary basis.

11 (c) CONDUCT OF DEMONSTRATION PROJECTS.—

12 (1) DEMONSTRATION SITES.—

13 (A) SELECTION OF DEMONSTRATION
14 SITES.—The Secretary shall conduct dem-
15 onstration projects at 6 demonstration sites.

16 (B) GEOGRAPHIC DIVERSITY.—Of the sites
17 described in subparagraph (A)—

18 (i) 3 shall be in rural areas; and

19 (ii) 3 shall be in urban areas.

20 (C) SITES LOCATED IN HPSAS.—At least 1
21 site described in clause (i) of subparagraph (B)
22 and at least 1 site described in clause (ii) of
23 such subparagraph shall be located in an area
24 that is designated under section 332(a)(1)(A) of
25 the Public Health Service Act (42 U.S.C.

1 254e(a)(1)(A)) as a health professional short-
2 age area.

3 (2) IMPLEMENTATION; DURATION.—

4 (A) IMPLEMENTATION.—The Secretary
5 shall not implement the demonstration projects
6 before October 1, 2004.

7 (B) DURATION.—The Secretary shall com-
8 plete the demonstration projects by the date
9 that is 3 years after the date on which the first
10 demonstration project is implemented.

11 (d) EVALUATION AND REPORT.—

12 (1) EVALUATION.—The Secretary shall conduct
13 an evaluation of the demonstration projects—

14 (A) to determine whether eligible bene-
15 ficiaries who use chiropractic services use a
16 lesser overall amount of items and services for
17 which payment is made under the medicare pro-
18 gram than eligible beneficiaries who do not use
19 such services;

20 (B) to determine the cost of providing pay-
21 ment for chiropractic services under the medi-
22 care program;

23 (C) to determine the satisfaction of eligible
24 beneficiaries participating in the demonstration

1 projects and the quality of care received by such
2 beneficiaries; and

3 (D) to evaluate such other matters as the
4 Secretary determines is appropriate.

5 (2) REPORT.—Not later than the date that is
6 1 year after the date on which the demonstration
7 projects conclude, the Secretary shall submit to Con-
8 gress a report on the evaluation conducted under
9 paragraph (1) together with such recommendations
10 for legislation or administrative action as the Sec-
11 retary determines is appropriate.

12 (e) WAIVER OF MEDICARE REQUIREMENTS.—The
13 Secretary shall waive compliance with such requirements
14 of the medicare program to the extent and for the period
15 the Secretary finds necessary to conduct the demonstra-
16 tion projects.

17 (f) FUNDING.—

18 (1) DEMONSTRATION PROJECTS.—

19 (A) IN GENERAL.—Subject to subpara-
20 graph (B) and paragraph (2), the Secretary
21 shall provide for the transfer from the Federal
22 Supplementary Insurance Trust Fund under
23 section 1841 of the Social Security Act (42
24 U.S.C. 1395t) of such funds as are necessary

for the costs of carrying out the demonstration projects under this section.

(B) LIMITATION.—In conducting the demonstration projects under this section, the Secretary shall ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration projects under this section were not implemented.

(2) EVALUATION AND REPORT.—There are authorized to be appropriated such sums as are necessary for the purpose of developing and submitting the report to Congress under subsection (d).

SEC. 441. MEDICARE HEALTH CARE QUALITY DEMONSTRATION PROGRAMS.

Title XVIII (42 U.S.C. 1395 et seq.) is amended by inserting after section 1866B the following new section:

“HEALTH CARE QUALITY DEMONSTRATION PROGRAM

“SEC. 1866C. (a) DEFINITIONS.—In this section:

“(1) BENEFICIARY.—The term ‘beneficiary’ means a beneficiary who is enrolled in the original medicare fee-for-service program under parts A and B or a beneficiary in a staff model or dedicated group model health maintenance organization under the Medicare+Choice program (or, on and after

1 January 1, 2006, under the Medicare Advantage pro-
 2 gram) under part C.

3 “(2) HEALTH CARE GROUP.—

4 “(A) IN GENERAL.—The term ‘health care
 5 group’ means—

6 “(i) a group of physicians that is or-
 7 ganized at least in part for the purpose of
 8 providing physician’s services under this
 9 title;

10 “(ii) an integrated health care delivery
 11 system that delivers care through coordi-
 12 nated hospitals, clinics, home health agen-
 13 cies, ambulatory surgery centers, skilled
 14 nursing facilities, rehabilitation facilities
 15 and clinics, and employed, independent, or
 16 contracted physicians; or

17 “(iii) an organization representing re-
 18 gional coalitions of groups or systems de-
 19 scribed in clause (i) or (ii).

20 “(B) INCLUSION.—As the Secretary deter-
 21 mines appropriate, a health care group may in-
 22 clude a hospital or any other individual or enti-
 23 ty furnishing items or services for which pay-
 24 ment may be made under this title that is affli-
 25 ated with the health care group under an ar-

1 rangement structured so that such hospital, in-
 2 dividual, or entity participates in a demonstra-
 3 tion project under this section.

4 “(3) PHYSICIAN.—Except as otherwise provided
 5 for by the Secretary, the term ‘physician’ means any
 6 individual who furnishes services that may be paid
 7 for as physicians’ services under this title.

8 “(b) DEMONSTRATION PROJECTS.—The Secretary
 9 shall establish a 5-year demonstration program under
 10 which the Secretary shall approve demonstration projects
 11 that examine health delivery factors that encourage the
 12 delivery of improved quality in patient care, including—

13 “(1) the provision of incentives to improve the
 14 safety of care provided to beneficiaries;

15 “(2) the appropriate use of best practice guide-
 16 lines by providers and services by beneficiaries;

17 “(3) reduced scientific uncertainty in the deliv-
 18 ery of care through the examination of variations in
 19 the utilization and allocation of services, and out-
 20 comes measurement and research;

21 “(4) encourage shared decision making between
 22 providers and patients;

23 “(5) the provision of incentives for improving
 24 the quality and safety of care and achieving the effi-
 25 cient allocation of resources;

1 “(6) the appropriate use of culturally and eth-
 2 nically sensitive health care delivery; and

3 “(7) the financial effects on the health care
 4 marketplace of altering the incentives for care deliv-
 5 ery and changing the allocation of resources.

6 “(c) ADMINISTRATION BY CONTRACT.—

7 “(1) IN GENERAL.—Except as otherwise pro-
 8 vided in this section, the Secretary may administer
 9 the demonstration program established under this
 10 section in a manner that is similar to the manner in
 11 which the demonstration program established under
 12 section 1866A is administered in accordance with
 13 section 1866B.

14 “(2) ALTERNATIVE PAYMENT SYSTEMS.—A
 15 health care group that receives assistance under this
 16 section may, with respect to the demonstration
 17 project to be carried out with such assistance, in-
 18 clude proposals for the use of alternative payment
 19 systems for items and services provided to bene-
 20 ficiaries by the group that are designed to—

21 “(A) encourage the delivery of high quality
 22 care while accomplishing the objectives de-
 23 scribed in subsection (b); and

“(B) streamline documentation and reporting requirements otherwise required under this title.

“(3) BENEFITS.—A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include modifications to the package of benefits available under the traditional fee-for-service program under parts A and B or the package of benefits available through a staff model or a dedicated group model health maintenance organization under part C. The criteria employed under the demonstration program under this section to evaluate outcomes and determine best practice guidelines and incentives shall not be used as a basis for the denial of medicare benefits under the demonstration program to patients against their wishes (or if the patient is incompetent, against the wishes of the patient’s surrogate) on the basis of the patient’s age or expected length of life or of the patient’s present or predicted disability, degree of medical dependency, or quality of life.

“(d) ELIGIBILITY CRITERIA.—To be eligible to receive assistance under this section, an entity shall—

“(1) be a health care group;

1 “(2) meet quality standards established by the
2 Secretary, including—

3 “(A) the implementation of continuous
4 quality improvement mechanisms that are
5 aimed at integrating community-based support
6 services, primary care, and referral care;

7 “(B) the implementation of activities to in-
8 crease the delivery of effective care to bene-
9 ficiaries;

10 “(C) encouraging patient participation in
11 preference-based decisions;

12 “(D) the implementation of activities to
13 encourage the coordination and integration of
14 medical service delivery; and

15 “(E) the implementation of activities to
16 measure and document the financial impact on
17 the health care marketplace of altering the in-
18 centives of health care delivery and changing
19 the allocation of resources; and

20 “(3) meet such other requirements as the Sec-
21 retary may establish.

22 “(e) WAIVER AUTHORITY.—The Secretary may waive
23 such requirements of titles XI and XVIII as may be nec-
24 essary to carry out the purposes of the demonstration pro-
25 gram established under this section.

1 “(f) BUDGET NEUTRALITY.—With respect to the 5-
 2 year period of the demonstration program under sub-
 3 section (b), the aggregate expenditures under this title for
 4 such period shall not exceed the aggregate expenditures
 5 that would have been expended under this title if the pro-
 6 gram established under this section had not been imple-
 7 mented. REMOVED BY THE NATIONAL ARCHIVES

8 “(g) NOTICE REQUIREMENTS.—In the case of an in-
 9 dividual that receives health care items or services under
 10 a demonstration program carried out under this section,
 11 the Secretary shall ensure that such individual is notified
 12 of any waivers of coverage or payment rules that are appli-
 13 cable to such individual under this title as a result of the
 14 participation of the individual in such program.

15 “(h) PARTICIPATION AND SUPPORT BY FEDERAL
 16 AGENCIES.—In carrying out the demonstration program
 17 under this section, the Secretary may direct—

18 “(1) the Director of the National Institutes of
 19 Health to expand the efforts of the Institutes to
 20 evaluate current medical technologies and improve
 21 the foundation for evidence-based practice;

22 “(2) the Administrator of the Agency for
 23 Healthcare Research and Quality to, where possible
 24 and appropriate, use the program under this section
 25 as a laboratory for the study of quality improvement

1 strategies and to evaluate, monitor, and disseminate
 2 information relevant to such program; and

3 “(3) the Administrator of the Centers for Medi-
 4 care & Medicaid Services and the Administrator of
 5 the Center for Medicare Choices to support linkages
 6 of relevant medicare data to registry information
 7 from participating health care groups for the bene-
 8 ficiary populations served by the participating
 9 groups, for analysis supporting the purposes of the
 10 demonstration program, consistent with the applica-
 11 ble provisions of the Health Insurance Portability
 12 and Accountability Act of 1996.

13 “(i) IMPLEMENTATION.—The Secretary shall not im-
 14 plement the demonstration program before October 1,
 15 2004.”.

16 **SEC. 442. MEDICARE COMPLEX CLINICAL CARE MANAGE-**
 17 **MENT PAYMENT DEMONSTRATION.**

18 (a) ESTABLISHMENT.—

19 (1) IN GENERAL.—The Secretary shall establish
 20 a demonstration program to make the medicare pro-
 21 gram more responsive to needs of eligible bene-
 22 ficiaries by promoting continuity of care, helping
 23 stabilize medical conditions, preventing or mini-
 24 mizing acute exacerbations of chronic conditions,

and reducing adverse health outcomes, such as adverse drug interactions related to polypharmacy.

(2) SITES.—The Secretary shall designate sites at which to conduct the demonstration program under this section, of which at least 3 shall be in an urban area and at least 1 shall be in a rural area. One of the sites shall be located in the State of Arkansas.

(3) DURATION.—The Secretary shall conduct the demonstration program under this section for a 3-year period.

(4) IMPLEMENTATION.—The Secretary shall not implement the demonstration program before October 1, 2004.

(b) PARTICIPANTS.—Any eligible beneficiary who resides in an area designated by the Secretary as a demonstration site under subsection (a)(2) may participate in the demonstration program under this section if such beneficiary identifies a principal care physician who agrees to manage the complex clinical care of the eligible beneficiary under the demonstration program.

(c) PRINCIPAL CARE PHYSICIAN RESPONSIBILITIES.—The Secretary shall enter into an agreement with each principal care physician who agrees to manage the complex clinical care of an eligible beneficiary under sub-

1 section (b) under which the principal care physician
2 shall—

3 (1) serve as the primary contact of the eligible
4 beneficiary in accessing items and services for which
5 payment may be made under the medicare program;

6 (2) maintain medical information related to
7 care provided by other health care providers who
8 provide health care items and services to the eligible
9 beneficiary, including clinical reports, medication
10 and treatments prescribed by other physicians, hos-
11 pital and hospital outpatient services, skilled nursing
12 home care, home health care, and medical equipment
13 services;

14 (3) monitor and advocate for the continuity of
15 care of the eligible beneficiary and the use of evi-
16 dence-based guidelines;

17 (4) promote self-care and family caregiver in-
18 volvement where appropriate;

19 (5) have appropriate staffing arrangements to
20 conduct patient self-management and other care co-
21 ordination activities as specified by the Secretary;

22 (6) refer the eligible beneficiary to community
23 services organizations and coordinate the services of
24 such organizations with the care provided by health
25 care providers; and

(7) meet such other complex care management requirements as the Secretary may specify.

(d) COMPLEX CLINICAL CARE MANAGEMENT FEE.—

(1) PAYMENT.—Under an agreement entered into under subsection (c), the Secretary shall pay to each principal care physician, on behalf of each eligible beneficiary under the care of that physician, the complex clinical care management fee developed by the Secretary under paragraph (2).

(2) DEVELOPMENT OF FEE.—The Secretary shall develop a complex care management fee under this paragraph that is paid on a monthly basis and which shall be payment in full for all the functions performed by the principal care physician under the demonstration program, including any functions performed by other qualified practitioners acting on behalf of the physician, appropriate staff under the supervision of the physician, and any other person under a contract with the physician, including any person who conducts patient self-management and caregiver education under subsection (c)(4).

(e) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Supplementary Insurance Trust Fund established under section 1841

1 of the Social Security Act (42 U.S.C. 1395t) of such
 2 funds as are necessary for the costs of carrying out
 3 the demonstration program under this section.

4 (2) BUDGET NEUTRALITY.—In conducting the
 5 demonstration program under this section, the Sec-
 6 retary shall ensure that the aggregate payments
 7 made by the Secretary do not exceed the amount
 8 which the Secretary would have paid if the dem-
 9 onstration program under this section was not im-
 10 plemented.

11 (f) WAIVER AUTHORITY.—The Secretary may waive
 12 such requirements of titles XI and XVIII of the Social
 13 Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as
 14 may be necessary for the purpose of carrying out the dem-
 15 onstration program under this section.

16 (g) REPORT.—Not later than 6 months after the
 17 completion of the demonstration program under this sec-
 18 tion, the Secretary shall submit to Congress a report on
 19 such program, together with recommendations for such
 20 legislation and administrative action as the Secretary de-
 21 termines to be appropriate.

22 (h) DEFINITIONS.—In this section:

23 (1) ACTIVITY OF DAILY LIVING.—The term “ac-
 24 tivity of daily living” means eating, toiling, transfer-
 25 ring, bathing, dressing, and continence.

(2) CHRONIC CONDITION.—The term “chronic condition” means a biological, physical, or mental condition that is likely to last a year or more, for which there is no known cure, for which there is a need for ongoing medical care, and which may affect an individual’s ability to carry out activities of daily living or instrumental activities of daily living, or both.

(3) ELIGIBLE BENEFICIARY.—The term “eligible beneficiary” means any individual who—

(A) is enrolled for benefits under part B of the medicare program;

(B) has at least 4 complex medical conditions (one of which may be cognitive impairment); and

(C) has—

(i) an inability to self-manage their care; or

(ii) a functional limitation defined as an impairment in 1 or more activity of daily living or instrumental activity of daily living.

(4) INSTRUMENTAL ACTIVITY OF DAILY LIVING.—The term “instrumental activity of daily living” means meal preparation, shopping, house-

1 keeping, laundry, money management, telephone
2 use, and transportation use.

3 (5) **MEDICARE PROGRAM.**—The term “medicare
4 program” means the health care program under title
5 XVIII of the Social Security Act (42 U.S.C. 1395 et
6 seq.).

7 (6) **PRINCIPAL CARE PHYSICIAN.**—The term
8 “principal care physician” means the physician with
9 primary responsibility for overall coordination of the
10 care of an eligible beneficiary (as specified in a writ-
11 ten plan of care) who may be a primary care physi-
12 cian or a specialist.

13 **SEC. 443. MEDICARE FEE-FOR-SERVICE CARE COORDINA-**
14 **TION DEMONSTRATION PROGRAM.**

15 (a) **ESTABLISHMENT.**—

16 (1) **IN GENERAL.**—The Secretary shall establish
17 a demonstration program to contract with qualified
18 care management organizations to provide health
19 risk assessment and care management services to el-
20 igible beneficiaries who receive care under the origi-
21 nal medicare fee-for-service program under parts A
22 and B of title XVIII of the Social Security Act to
23 eligible beneficiaries.

24 (2) **SITES.**—The Secretary shall designate 6
25 sites at which to conduct the demonstration program

under this section. In selecting sites under this paragraph, the Secretary shall give preference to sites located in rural areas.

(3) DURATION.—The Secretary shall conduct the demonstration program under this section for a 5-year period.

(4) IMPLEMENTATION.—The Secretary shall not implement the demonstration program before October 1, 2004.

(b) PARTICIPANTS.—Any eligible beneficiary who resides in an area designated by the Secretary as a demonstration site under subsection (a)(2) may participate in the demonstration program under this section if such beneficiary identifies a care management organization who agrees to furnish care management services to the eligible beneficiary under the demonstration program.

(c) CONTRACTS WITH CMOS.—

(1) IN GENERAL.—The Secretary shall enter into a contract with care management organizations to provide care management services to eligible beneficiaries residing in the area served by the care management organization.

(2) CANCELLATION.—The Secretary may cancel a contract entered into under paragraph (1) if the care management organization does not meet nego-

1 tiated savings or quality outcomes targets for the
2 year.

3 (3) NUMBER OF CMOS.—The Secretary may
4 contract with more than 1 care management organi-
5 zation in a geographic area.

6 (d) PAYMENT TO CMOS.—

7 (1) PAYMENT.—Under an contract entered into
8 under subsection (c), the Secretary shall pay care
9 management organizations a fee for which the care
10 management organization is partially at risk based
11 on bids submitted by care management organiza-
12 tions.

13 (2) PORTION OF PAYMENT AT RISK.—The Sec-
14 retary shall establish a benchmark for quality and
15 cost against which the results of the care manage-
16 ment organization are to be measured. The Sec-
17 retary may not pay a care management organization
18 the portion of the fee described in paragraph (1)
19 that is at risk unless the Secretary determines that
20 the care management organization has met the
21 agreed upon savings and outcomes targets for the
22 year.

23 (e) FUNDING.—

24 (1) IN GENERAL.—The Secretary shall provide
25 for the transfer from the Federal Hospital Insurance

1 Trust Fund under section 1817 of the Social Secu-
 2 rity Act (42 U.S.C. 1395i) and the Federal Supple-
 3 mentary Insurance Trust Fund established under
 4 section 1841 of such Act (42 U.S.C. 1395t), in such
 5 proportion as the Secretary determines to be appro-
 6 priate, of such funds as are necessary for the costs
 7 of carrying out the demonstration program under
 8 this section.

9 (2) BUDGET NEUTRALITY.—In conducting the
 10 demonstration program under this section, the Sec-
 11 retary shall ensure that the aggregate payments
 12 made by the Secretary do not exceed the amount
 13 which the Secretary would have paid if the dem-
 14 onstration program under this section was not im-
 15 plemented.

16 (f) WAIVER AUTHORITY.—

17 (1) IN GENERAL.—The Secretary may waive
 18 such requirements of titles XI and XVIII of the So-
 19 cial Security Act (42 U.S.C. 1301 et seq.; 1395 et
 20 seq.) as may be necessary for the purpose of car-
 21 rying out the demonstration program under this sec-
 22 tion.

23 (2) WAIVER OF MEDIGAP PREEMPTIONS.—The
 24 Secretary shall waive any provision of section 1882
 25 of the Social Security Act that would prevent an in-

1 surance carrier described in subsection (h)(3)(D)
2 from participating in the demonstration program
3 under this section.

4 (g) REPORT.—Not later than 6 months after the
5 completion of the demonstration program under this sec-
6 tion, the Secretary shall submit to Congress a report on
7 such program, together with recommendations for such
8 legislation and administrative action as the Secretary de-
9 termines to be appropriate.

10 (h) DEFINITIONS.—In this section:

11 (1) CARE MANAGEMENT SERVICES.—The term
12 “care management services” means services that are
13 furnished to an eligible beneficiary (as defined in
14 paragraph (2)) by a care management organization
15 (as defined in paragraph (3)) in accordance with
16 guidelines established by the Secretary that are con-
17 sistent with guidelines established by the American
18 Geriatrics Society.

19 (2) ELIGIBLE BENEFICIARY.—The term “eligi-
20 ble beneficiary” means an individual who is—

21 (A) entitled to (or enrolled for) benefits
22 under part A and enrolled for benefits under
23 part B of the Social Security Act (42 U.S.C.
24 1395c et seq.; 1395j et seq.);

(B) not enrolled with a Medicare+Choice plan or a MedicareAdvantage plan under part C; and

(C) at high-risk (as defined by the Secretary, but including eligible beneficiaries with multiple sclerosis or another disabling chronic condition, eligible beneficiaries residing in a nursing home or at risk for nursing home placement, or eligible beneficiaries eligible for assistance under a State plan under title XIX).

(3) CARE MANAGEMENT ORGANIZATION.—The term “care management organization” means an organization that meets such qualifications as the Secretary may specify and includes any of the following:

(A) A physician group practice, hospital, home health agency, or hospice program.

(B) A disease management organization.

(C) A Medicare+Choice or MedicareAdvantage organization.

(D) Insurance carriers offering medicare supplemental policies under section 1882 of the Social Security Act (42 U.S.C. 1395ss).

(E) Such other entity as the Secretary determines to be appropriate.

1 **SEC. 444. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN**
2 **PAYMENTS FOR PHYSICIANS' SERVICES.**

3 (a) STUDY.—The Comptroller General of the United
4 States shall conduct a study of differences in payment
5 amounts under the physician fee schedule under section
6 1848 of the Social Security Act (42 U.S.C. 1395w-4) for
7 physicians' services in different geographic areas. Such
8 study shall include—

9 (1) an assessment of the validity of the geo-
10 graphic adjustment factors used for each component
11 of the fee schedule;

12 (2) an evaluation of the measures used for such
13 adjustment, including the frequency of revisions;

14 (3) an evaluation of the methods used to deter-
15 mine professional liability insurance costs used in
16 computing the malpractice component, including a
17 review of increases in professional liability insurance
18 premiums and variation in such increases by State
19 and physician specialty and methods used to update
20 the geographic cost of practice index and relative
21 weights for the malpractice component;

22 (4) an evaluation of whether there is a sound
23 economic basis for the implementation of the adjust-
24 ment under subparagraphs (E) and (F) of section
25 1848(e)(1) of the Social Security Act (42 U.S.C.

1 1395w-4(e)(1)), as added by section 421, in those
 2 areas in which the adjustment applies;

3 (5) an evaluation of the effect of such adjust-
 4 ment on physician location and retention in areas af-
 5 fected by such adjustment, taking into account—

6 (A) differences in recruitment costs and re-
 7 tention rates for physicians, including special-
 8 ists, between large urban areas and other areas;
 9 and

10 (B) the mobility of physicians, including
 11 specialists, over the last decade;

12 (6) an evaluation of the appropriateness of ex-
 13 tending such adjustment or making such adjustment
 14 permanent;

15 (7) an evaluation of the adjustment of the work
 16 geographic practice cost index required under section
 17 1848(e)(1)(A)(iii) of the Social Security Act (42
 18 U.S.C. 1395w-4(e)(1)(A)(iii)) to reflect $\frac{1}{4}$ of the
 19 area cost difference in physician work;

20 (8) an evaluation of the effect of the adjust-
 21 ment described in paragraph (7) on physician loca-
 22 tion and retention in higher than average cost-of-liv-
 23 ing areas, taking into account difference in recruit-
 24 ment costs and retention rates for physicians, in-
 25 cluding specialists; and

1 (9) an evaluation of the appropriateness of the
 2 $\frac{1}{4}$ adjustment for the work geographic practice cost
 3 index.”.

4 (b) REPORT.—Not later than 1 year after the date
 5 of enactment of this Act, the Comptroller General of the
 6 United States shall submit to Congress a report on the
 7 study conducted under subsection (a). The report shall in-
 8 clude recommendations regarding the use of more current
 9 data in computing geographic cost of practice indices as
 10 well as the use of data directly representative of physi-
 11 cians' costs (rather than proxy measures of such costs).

12 **SEC. 445. IMPROVED PAYMENT FOR CERTAIN MAMMOG-**
 13 **RAPHY SERVICES.**

14 (a) EXCLUSION FROM OPD FEE SCHEDULE.—Sec-
 15 tion 1833(t)(1)(B)(iv) (42 U.S.C. 13951(t)(1)(B)(iv)) is
 16 amended by inserting before the period at the end the fol-
 17 lowing: “and does not include screening mammography (as
 18 defined in section 1861(jj)) and unilateral and bilateral
 19 diagnostic mammography”.

20 (b) EFFECTIVE DATE.—The amendment made by
 21 subsection (a) shall apply to mammography performed on
 22 or after January 1, 2005.

1 **SEC. 446. IMPROVEMENT OF OUTPATIENT VISION SERV-**
 2 **ICES UNDER PART B.**

3 (a) COVERAGE UNDER PART B.—Section 1861(s)(2)
 4 (42 U.S.C. 1395x(s)(2)) is amended—

5 (1) in subparagraph (U), by striking “and”
 6 after the semicolon at the end;

7 (2) in subparagraph (V)(iii), by adding “and”
 8 after the semicolon at the end; and

9 (3) by adding at the end the following new sub-
 10 paragraph:

11 “(W) vision rehabilitation services (as defined
 12 in subsection (ww)(1));”.

13 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
 14 1395x) is amended by adding at the end the following new
 15 subsection:

16 “Vision Rehabilitation Services; Vision Rehabilitation
 17 Professional

18 “(ww)(1)(A) The term ‘vision rehabilitation services’
 19 means rehabilitative services (as determined by the Sec-
 20 retary in regulations) furnished—

21 “(i) to an individual diagnosed with a vision im-
 22 pairment (as defined in paragraph (6));

23 “(ii) pursuant to a plan of care established by
 24 a qualified physician (as defined in subparagraph
 25 (C)) or by a qualified occupational therapist that is
 26 periodically reviewed by a qualified physician;

1 “(iii) in an appropriate setting (including the
2 home of the individual receiving such services if
3 specified in the plan of care); and

4 “(iv) by any of the following individuals:

5 “(I) A qualified physician.

6 “(II) A qualified occupational therapist.

7 “(III) A vision rehabilitation professional
8 (as defined in paragraph (2)) while under the
9 general supervision (as defined in subparagraph
10 (D)) of a qualified physician.

11 “(B) In the case of vision rehabilitation services fur-
12 nished by a vision rehabilitation professional, the plan of
13 care may only be established and reviewed by a qualified
14 physician.

15 “(C) The term ‘qualified physician’ means—

16 “(i) a physician (as defined in subsection
17 (r)(1)) who is an ophthalmologist; or

18 “(ii) a physician (as defined in subsection (r)(4)
19 (relating to a doctor of optometry)).

20 “(D) The term ‘general supervision’ means, with re-
21 spect to a vision rehabilitation professional, overall direc-
22 tion and control of that professional by the qualified physi-
23 cian who established the plan of care for the individual,
24 but the presence of the qualified physician is not required

1 during the furnishing of vision rehabilitation services by
2 that professional to the individual.

3 “(2) The term ‘vision rehabilitation professional’
4 means any of the following individuals: 101.0011(4)(2)

5 “(Λ) An orientation and mobility specialist (as
6 defined in paragraph (3)).

7 “(B) A rehabilitation teacher (as defined in

8 paragraph (4)).” *— CHIT*

9 “(C) A low vision therapist (as defined in para-

10 graph (5)).”

11 “(3) The term ‘orientation and mobility specialist’
12 means an individual who—

“(A) if a State requires licensure or certification of orientation and mobility specialists, is licensed or certified by that State as an orientation and mobility specialist;

“(B)(i) holds a baccalaureate or higher degree from an accredited college or university in the United States (or an equivalent foreign degree) with a concentration in orientation and mobility; and

“(ii) has successfully completed 350 hours of clinical practicum under the supervision of an orientation and mobility specialist and has furnished not less than 9 months of supervised full-time orientation and mobility services; *5-33910-00000-0-0000*

1 “(C) has successfully completed the national ex-
 2 amination in orientation and mobility administered
 3 by the Academy for Certification of Vision Rehabili-
 4 tation and Education Professionals; and ~~and~~

5 “(D) meets such other criteria as the Secretary
 6 establishes.

7 “(4) The term ‘rehabilitation teacher’ means an indi-
 8 vidual who—

9 “(A) if a State requires licensure or certifi-
 10 cation of rehabilitation teachers, is licensed or cer-
 11 tified by the State as a rehabilitation teacher;

12 “(B)(i) holds a baccalaureate or higher degree
 13 from an accredited college or university in the
 14 United States (or an equivalent foreign degree) with
 15 a concentration in rehabilitation teaching, or holds
 16 such a degree in a health field; and

17 “(ii) has successfully completed 350 hours of
 18 clinical practicum under the supervision of a reha-
 19 bilitation teacher and has furnished not less than 9
 20 months of supervised full-time rehabilitation teach-
 21 ing services;

22 “(C) has successfully completed the national ex-
 23 amination in rehabilitation teaching administered by
 24 the Academy for Certification of Vision Rehabilita-
 25 tion and Education Professionals; and

1 “(D) meets such other criteria as the Secretary
2 establishes. *§ 202.10(b)(5)(ii)(D)*

3 “(5) The term ‘low vision therapist’ means an indi-
4 vidual who—

5 “(A) if a State requires licensure or certifi-
6 cation of low vision therapists, is licensed or certified
7 by the State as a low vision therapist;

8 “(B)(i) holds a baccalaureate or higher degree
9 from an accredited college or university in the
10 United States (or an equivalent foreign degree) with
11 a concentration in low vision therapy, or holds such
12 a degree in a health field; and *§ 202.10(b)(5)(ii)(B)(i)*

13 “(ii) has successfully completed 350 hours of
14 clinical practicum under the supervision of a physi-
15 cian, and has furnished not less than 9 months of
16 supervised full-time low vision therapy services;

17 “(C) has successfully completed the national ex-
18 amination in low vision therapy administered by the
19 Academy for Certification of Vision Rehabilitation
20 and Education Professionals; and

21 “(D) meets such other criteria as the Secretary
22 establishes. *§ 202.10(b)(5)(ii)(D)*

23 “(6) The term ‘vision impairment’ means vision loss
24 that constitutes a significant limitation of visual capability
25 resulting from disease, trauma, or a congenital or degen-

1 erative condition that cannot be corrected by conventional
 2 means, including refractive correction, medication, or sur-
 3 gery, and that is manifested by 1 or more of the following:

4 “(A) Best corrected visual acuity of less than
 5 20/60, or significant central field defect.

6 “(B) Significant peripheral field defect includ-
 7 ing homonymous or heteronymous bilateral visual
 8 field defect or generalized contraction or constriction
 9 of field.

10 “(C) Reduced peak contrast sensitivity in con-
 11 junction with a condition described in subparagraph
 12 (A) or (B).

13 “(D) Such other diagnoses, indications, or other
 14 manifestations as the Secretary may determine to be
 15 appropriate.”.

16 (c) PAYMENT UNDER PART B.—

17 (1) PHYSICIAN FEE SCHEDULE.—Section
 18 1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) is amended
 19 by inserting “(2)(W),” after “(2)(S),”.

20 (2) CARVE OUT FROM HOSPITAL OUTPATIENT
 21 DEPARTMENT PROSPECTIVE PAYMENT SYSTEM.—
 22 Section 1833(t)(1)(B)(iv) (42 U.S.C.
 23 1395l(t)(1)(B)(iv)) is amended by inserting “vision
 24 rehabilitation services (as defined in section
 25 1861(w)(1)) or” after “does not include”.

(3) CLARIFICATION OF BILLING REQUIREMENTS.—The first sentence of section 1842(b)(6) of such Act (42 U.S.C. 1395u(b)(6)) is amended—

(A) by striking “and” before “(G)”;

(B) by inserting before the period the following: “, and (H) in the case of vision rehabilitation services (as defined in section 1861(w)(1)) furnished by a vision rehabilitation professional (as defined in section 1861(w)(2)) while under the general supervision (as defined in section 1861(w)(1)(D)) of a qualified physician (as defined in section 1861(w)(1)(C)), payment shall be made to (i) the qualified physician or (ii) the facility (such as a rehabilitation agency, a clinic, or other facility) through which such services are furnished under the plan of care if there is a contractual arrangement between the vision rehabilitation professional and the facility under which the facility submits the bill for such services”.

(d) PLAN OF CARE.—Section 1835(a)(2) (42 U.S.C. 1395n(a)(2)) is amended—

(1) in subparagraph (E), by striking “and” after the semicolon at the end;

1 (2) in subparagraph (F), by striking the period
 2 at the end and inserting “; and”; and
 3 (3) by inserting after subparagraph (F) the fol-
 4 lowing new subparagraph:

5 “(G) in the case of vision rehabilitation
 6 services, (i) such services are or were required
 7 because the individual needed vision rehabilita-
 8 tion services, (ii) an individualized, written plan
 9 for furnishing such services has been estab-
 10 lished (I) by a qualified physician (as defined in
 11 section 1861(w)(1)(C)), (II) by a qualified oc-
 12 cupational therapist, or (III) in the case of such
 13 services furnished by a vision rehabilitation pro-
 14 fessional, by a qualified physician, (iii) the plan
 15 is periodically reviewed by the qualified physi-
 16 cian, and (iv) such services are or were fur-
 17 nished while the individual is or was under the
 18 care of the qualified physician.”.

19 (e) RELATIONSHIP TO REHABILITATION ACT OF
 20 1973.—The provision of vision rehabilitation services
 21 under the medicare program under title XVIII (42 U.S.C.
 22 1395 et seq.) shall not be taken into account for any pur-
 23 pose under the Rehabilitation Act of 1973 (29 U.S.C. 701
 24 et seq.).

25 (f) EFFECTIVE DATE.—

(1) INTERIM, FINAL REGULATIONS.—The Secretary shall publish a rule under this section in the Federal Register by not later than 180 days after the date of enactment of this Act to carry out the provisions of this section. Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period for public comment of not less than 60 days.

(2) CONSULTATION.—The Secretary shall consult with the National Vision Rehabilitation Cooperative, the Association for Education and Rehabilitation of the Blind and Visually Impaired, the Academy for Certification of Vision Rehabilitation and Education Professionals, the American Academy of Ophthalmology, the American Occupational Therapy Association, the American Optometric Association, and such other qualified professional and consumer organizations as the Secretary determines appropriate in promulgating regulations to carry out this section.

**SEC. 447. GAO STUDY AND REPORT ON THE PROPAGATION
OF CONCIERGE CARE.**

(a) STUDY.—

1 (1) IN GENERAL.—The Comptroller General of
 2 the United States shall conduct a study on concierge
 3 care (as defined in paragraph (2)) to determine the
 4 extent to which such care—

5 (A) is used by medicare beneficiaries (as
 6 defined in section 1802(b)(5)(A) of the Social
 7 Security Act (42 U.S.C. 1395a(b)(5)(A))); and
 8 (B) has impacted upon the access of medi-
 9 care beneficiaries (as so defined) to items and
 10 services for which reimbursement is provided
 11 under the medicare program under title XVIII
 12 of the Social Security Act (42 U.S.C. 1395 et
 13 seq.).

14 (2) CONCIERGE CARE.—In this section, the
 15 term “concierge care” means an arrangement under
 16 which, as a prerequisite for the provision of a health
 17 care item or service to an individual, a physician,
 18 practitioner (as described in section 1842(b)(18)(C)
 19 of the Social Security Act (42 U.S.C.
 20 1395u(b)(18)(C))), or other individual—

21 (A) charges a membership fee or another
 22 incidental fee to an individual desiring to re-
 23 ceive the health care item or service from such
 24 physician, practitioner, or other individual; or

(B) requires the individual desiring to receive the health care item or service from such physician, practitioner, or other individual to purchase an item or service.

(b) REPORT.—Not later than the date that is 12 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the study conducted under subsection (a)(1) together with such recommendations for legislative or administrative action as the Comptroller General determines to be appropriate.

SEC. 448. COVERAGE OF MARRIAGE AND FAMILY THERAPIST SERVICES AND MENTAL HEALTH COUNSELOR SERVICES UNDER PART B OF THE MEDICARE PROGRAM.

(a) COVERAGE OF SERVICES.—

(1) IN GENERAL.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

(A) in subparagraph (U), by striking “and” after the semicolon at the end;

(B) in subparagraph (V)(iii), by inserting “and” after the semicolon at the end; and

(C) by adding at the end the following new subparagraph:

1 “(W) marriage and family therapist services (as
 2 defined in subsection (ww)(1)) and mental health
 3 counselor services (as defined in subsection
 4 (ww)(3));”.

5 (2) DEFINITIONS.—Section 1861 (42 U.S.C.
 6 1395x) is amended by adding at the end the fol-
 7 lowing new subsection:

8 “Marriage and Family Therapist Services; Marriage and
 9 Family Therapist; Mental Health Counselor Serv-
 10 ices; Mental Health Counselor

11 “(ww)(1) The term ‘marriage and family therapist
 12 services’ means services performed by a marriage and
 13 family therapist (as defined in paragraph (2)) for the diag-
 14 nosis and treatment of mental illnesses, which the mar-
 15 riage and family therapist is legally authorized to perform
 16 under State law (or the State regulatory mechanism pro-
 17 vided by State law) of the State in which such services
 18 are performed, as would otherwise be covered if furnished
 19 by a physician or as an incident to a physician’s profes-
 20 sional service, but only if no facility or other provider
 21 charges or is paid any amounts with respect to the fur-
 22 nishing of such services.

23 “(2) The term ‘marriage and family therapist’ means
 24 an individual who—

“(A) possesses a master’s or doctoral degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law;

“(B) after obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and

“(C) in the case of an individual performing services in a State that provides for licensure or certification of marriage and family therapists, is licensed or certified as a marriage and family therapist in such State.

“(3) The term ‘mental health counselor services’ means services performed by a mental health counselor (as defined in paragraph (4)) for the diagnosis and treatment of mental illnesses which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by the State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as incident to a physician’s professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

“(4) The term ‘mental health counselor’ means an individual who—

1 “(A) possesses a master’s or doctor’s degree in
2 mental health counseling or a related field; H-2

3 “(B) after obtaining such a degree has per-
4 formed at least 2 years of supervised mental health
5 counselor practice; and .

6 “(C) in the case of an individual performing
7 services in a State that provides for licensure or cer-
8 tification of mental health counselors or professional
9 counselors, is licensed or certified as a mental health
10 counselor or professional counselor in such State.”.

11 (3) PROVISION FOR PAYMENT UNDER PART
12 B.—Section 1832(a)(2)(B) (42 U.S.C.
13 1395k(a)(2)(B)) is amended by adding at the end
14 the following new clause: 1395k(a)(2)(B) - D.

15 “(v) marriage and family therapist
16 services and mental health counselor serv-
17 ices;”. H-200

18 (4) AMOUNT OF PAYMENT.—Section 1833(a)(1)
19 (42 U.S.C. 1395l(a)(1)) is amended— H-200 9001 200

20 (A) by striking “and (U)” and inserting
21 “(U)”; and H-200 1000b

22 (B) by inserting before the semicolon at
23 the end the following: “, and (V) with respect
24 to marriage and family therapist services and
25 mental health counselor services under section

1 1861(s)(2)(W), the amounts paid shall be 80
 2 percent of the lesser of the actual charge for
 3 the services or 75 percent of the amount deter-
 4 mined for payment of a psychologist under sub-
 5 paragraph (L)".

6 (5) EXCLUSION OF MARRIAGE AND FAMILY
 7 THERAPIST SERVICES AND MENTAL HEALTH COUN-
 8 SELOR SERVICES FROM SKILLED NURSING FACILITY
 9 PROSPECTIVE PAYMENT SYSTEM.—Section
 10 1888(e)(2)(A)(ii) (42 U.S.C. 1395yy(e)(2)(A)(ii)), as
 11 amended in section 301(a), is amended by inserting
 12 “marriage and family therapist services (as defined
 13 in subsection (ww)(1)), mental health counselor serv-
 14 ices (as defined in section 1861(ww)(3)),” after
 15 “qualified psychologist services,”.

16 (6) INCLUSION OF MARRIAGE AND FAMILY
 17 THERAPISTS AND MENTAL HEALTH COUNSELORS AS
 18 PRACTITIONERS FOR ASSIGNMENT OF CLAIMS.—Sec-
 19 tion 1842(b)(18)(C) (42 U.S.C. 1395u(b)(18)(C)) is
 20 amended by adding at the end the following new
 21 clauses:

22 “(vii) A marriage and family therapist (as de-
 23 fined in section 1861(ww)(2)).

24 “(viii) A mental health counselor (as defined in
 25 section 1861(ww)(4)).”.

1 (b) COVERAGE OF CERTAIN MENTAL HEALTH SERV-
 2 ICES PROVIDED IN CERTAIN SETTINGS.—

3 (1) RURAL HEALTH CLINICS AND FEDERALLY
 4 QUALIFIED HEALTH CENTERS.—Section
 5 1861(aa)(1)(B) (42 U.S.C. 1395x(aa)(1)(B)) is
 6 amended by striking “or by a clinical social worker
 7 (as defined in subsection (hh)(1)),” and inserting “,
 8 by a clinical social worker (as defined in subsection
 9 (hh)(1)), by a marriage and family therapist (as de-
 10 fined in subsection (ww)(2)), or by a mental health
 11 counselor (as defined in subsection (ww)(4)),”.

12 (2) HOSPICE PROGRAMS.—Section
 13 1861(dd)(2)(B)(i)(III) (42 U.S.C.
 14 1395x(dd)(2)(B)(i)(III)) is amended by inserting “or
 15 a marriage and family therapist (as defined in sub-
 16 section (ww)(2))” after “social worker”.

17 (c) AUTHORIZATION OF MARRIAGE AND FAMILY
 18 THERAPISTS TO DEVELOP DISCHARGE PLANS FOR POST-
 19 HOSPITAL SERVICES.—Section 1861(ee)(2)(G) (42
 20 U.S.C. 1395x(ee)(2)(G)) is amended by inserting “mar-
 21 riage and family therapist (as defined in subsection
 22 (ww)(2)),” after “social worker,”.

23 (d) EFFECTIVE DATE.—The amendments made by
 24 this section shall apply with respect to services furnished
 25 on or after January 1, 2004.

1 **SEC. 449. MEDICARE DEMONSTRATION PROJECT FOR DI-**
2 **RECT ACCESS TO PHYSICAL THERAPY SERV-**
3 **ICES.**

4 (a) IN GENERAL.—The Secretary shall conduct a
5 demonstration project under this section (in this section
6 referred to as the “project”) to demonstrate the impact
7 of allowing medicare fee-for-service beneficiaries direct ac-
8 cess to outpatient physical therapy services and physical
9 therapy services furnished as comprehensive rehabilitation
10 facility services on—

11 (1) costs under the medicare program under
12 title XVIII of the Social Security Act; and

13 (2) the satisfaction of beneficiaries receiving
14 such services.

15 (b) DEADLINE FOR ESTABLISHMENT; DURATION;
16 SITES.—

17 (1) DEADLINE.—The Secretary shall establish
18 the project not later than 1 year after the date of
19 enactment of this Act.

20 (2) DURATION; SITES.—The project shall—

21 (A) be conducted for a period of 3 years;

22 (B) include sites in at least 5 States; and

23 (C) to the extent feasible, be conducted on

24 a statewide basis in each State included under

25 subparagraph (B).

1 (3) EARLY TERMINATION.—Notwithstanding
 2 paragraph (2)(A), the Secretary may terminate the
 3 operation of the project at a site before the end of
 4 the 3-year period specified in such paragraph if the
 5 Secretary determines, based on actual data, that the
 6 total amount expended for all services under this
 7 title for individuals at such site for a 12-month pe-
 8 riod are greater than the total amount that would
 9 have been expended for such services for such indi-
 10 viduals for such period but for the operation of the
 11 project at such site.

12 (c) WAIVER OF MEDICARE REQUIREMENTS.—The
 13 Secretary shall waive compliance with such requirements
 14 of the medicare program under title XVIII of the Social
 15 Security Act to the extent and for the period the Secretary
 16 finds necessary to conduct the demonstration project.

17 (d) EVALUATIONS AND REPORTS.—

18 (1) EVALUATIONS.—

19 (A) IN GENERAL.—The Secretary shall
 20 conduct interim and final evaluations of the
 21 project.

22 (B) FOCUS.—The evaluations conducted
 23 under paragraph (1) shall—

24 (i) focus on the impact of the project
 25 on program costs under title XVIII of the

Social Security Act and patient satisfaction
with health care items and services for
which payment is made under such title;

and (ii) include comparisons, with respect
to episodes of care involving direct access
to physical therapy services and episodes of
care involving a physician referral for such
services, of—

(I) the average number of claims
paid per episode for outpatient phys-
ical therapy services and physical
therapy services furnished as com-
prehensive outpatient rehabilitation
facility services;

(II) the average number of physi-
cian office visits per episode; and

(III) the average expenditures
under such title per episode.

(2) INTERIM AND FINAL REPORTS.—The Sec-
retary shall submit to the Committee on Finance of
the Senate and the Committees on Ways and Means
and Energy and Commerce of the House of Rep-
resentatives reports on the evaluations conducted
under paragraph (1) by—

1 (A) in the case of the report on the interim
2 evaluation, not later than the end of the second
3 year the project has been in operation; and

4 (B) in the case of the report on the final
5 evaluation, not later than 180 days after the
6 closing date of the project.

7 (3) FUNDING FOR EVALUATION.—There are au-
8 thorized to be appropriated such sums as may be
9 necessary to provide for the evaluations and reports
10 required by this subsection.

11 (e) DEFINITIONS.—In this section:

12 (1) COMPREHENSIVE OUTPATIENT REHABILITA-
13 TION SERVICES.—Subject to paragraph (2), the term
14 “comprehensive outpatient rehabilitation services”
15 has the meaning given to such term in section
16 1861(cc) of the Social Security Act (42 U.S.C.
17 1395x(cc)).

18 (2) DIRECT ACCESS.—The term “direct access”
19 means, with respect to outpatient physical therapy
20 services and physical therapy services furnished as
21 comprehensive outpatient rehabilitation facility serv-
22 ices, coverage of and payment for such services in
23 accordance with the provisions of title XVIII of the
24 Social Security Act, except that sections 1835(a)(2),
25 1861(p), and 1861(cc) of such Act (42 U.S.C.

1 1395n(a)(2), 1395x(p), and 1395x(cc), respectively)
 2 shall be applied—

3 (A) without regard to any requirement
 4 that—

5 (i) an individual be under the care of
 6 (or referred by) a physician; or

7 (ii) services be provided under the su-
 8 pervision of a physician; and

9 (B) by allowing a physician or a qualified
 10 physical therapist to satisfy any requirement
 11 for—

12 (i) certification and recertification;

13 and

14 (ii) establishment and periodic review
 15 of a plan of care.

16 (3) FEE-FOR-SERVICE MEDICARE BENE-
 17 FICIARY.—The term “fee-for-service medicare bene-
 18 ficiary” means an individual who—

19 (A) is enrolled under part B of title XVIII
 20 of the Social Security Act (42 U.S.C. 1395j et
 21 seq.); and

22 (B) is not enrolled in—

23 (i) a Medicare+Choice plan under
 24 part C of such title (42 U.S.C. 1395w-21
 25 et seq.);

1 (ii) a plan offered by an eligible orga-
 2 nization under section 1876 of such Act
 3 (42 U.S.C. 1395mm);

4 (iii) a program of all-inclusive care for
 5 the elderly (PACE) under section 1894 of
 6 such Act (42 U.S.C. 1395eee); or

7 (iv) a social health maintenance orga-
 8 nization (SHMO) demonstration project
 9 established under section 4018(b) of the
 10 Omnibus Budget Reconciliation Act of
 11 1987 (Public Law 100-203).

12 (4) OUTPATIENT PHYSICAL THERAPY SERV-
 13 ICES.—Subject to paragraph (2), the term “out-
 14 patient physical therapy services” has the meaning
 15 given to such term in section 1861(p) of the Social
 16 Security Act (42 U.S.C. 1395x(p)), except that such
 17 term shall not include the speech-language pathology
 18 services described in the fourth sentence of such sec-
 19 tion.

20 (5) PHYSICIAN.—The term “physician” has the
 21 meaning given to such term in section 1861(r)(1) of
 22 such Act (42 U.S.C. 1395x(r)(1)).

23 (6) QUALIFIED PHYSICAL THERAPIST.—The
 24 term “qualified physical therapist” has the meaning
 25 given to such term for purposes of section 1861(p)

of such Act (42 U.S.C. 1395x(p)), as in effect on the date of enactment of this Act.

SEC. 450. DEMONSTRATION PROJECT TO CLARIFY THE DEFINITION OF HOMEBOUND.

(a) DEMONSTRATION PROJECT.—Not later than 180 days after the date of enactment of this Act, the Secretary shall conduct a two-year demonstration project under part B of title XVIII of the Social Security Act under which medicare beneficiaries with chronic conditions described in subsection (b) are deemed to be homebound for purposes of receiving home health services under the medicare program.

(b) MEDICARE BENEFICIARY DESCRIBED.—For purposes of subsection (a), a medicare beneficiary is eligible to be deemed to be homebound, without regard to the purpose, frequency, or duration of absences from the home, if the beneficiary—

(1) has been certified by one physician as an individual who has a permanent and severe condition that will not improve;

(2) requires the individual to receive assistance from another individual with at least 3 out of the 5 activities of daily living for the rest of the individual's life;

(3) requires 1 or more home health services to achieve a functional condition that gives the individual the ability to leave home; and

(4) requires technological assistance or the assistance of another person to leave the home.

(c) DEMONSTRATION PROJECT SITES.—The demonstration project established under this section shall be conducted in 3 States selected by the Secretary to represent the Northeast, Midwest, and Western regions of the United States.

(d) LIMITATION ON NUMBER OF PARTICIPANTS.—The aggregate number of such beneficiaries that may participate in the project may not exceed 15,000.

(e) DATA.—The Secretary shall collect such data on the demonstration project with respect to the provision of home health services to medicare beneficiaries that relates to quality of care, patient outcomes, and additional costs, if any, to the medicare program.

(f) REPORT TO CONGRESS.—Not later than 1 year after the date of the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project using the data collected under subsection (e) and shall include—

1 (1) an examination of whether the provision of
2 home health services to medicare beneficiaries under
3 the project—

4 (A) adversely effects the provision of home
5 health services under the medicare program; or

6 (B) directly causes an unreasonable in-
7 crease of expenditures under the medicare pro-
8 gram for the provision of such services that is
9 directly attributable to such clarification;

10 (2) the specific data evidencing the amount of
11 any increase in expenditures that is a directly attrib-
12 utable to the demonstration project (expressed both
13 in absolute dollar terms and as a percentage) above
14 expenditures that would otherwise have been in-
15 curred for home health services under the medicare
16 program; and

17 (3) specific recommendations to exempt perma-
18 nently and severely disabled homebound beneficiaries
19 from restrictions on the length, frequency and pur-
20 pose of their absences from the home to qualify for
21 home health services without incurring additional
22 unreasonable costs to the medicare program.

23 (g) WAIVER AUTHORITY.—The Secretary shall waive
24 compliance with the requirements of title XVIII of the So-
25 cial Security Act (42 U.S.C. 1395 et seq.) to such extent

1 and for such period as the Secretary determines is nec-
 2 essary to conduct demonstration projects.

3 (h) CONSTRUCTION.—Nothing in this section shall be
 4 construed as waiving any applicable civil monetary pen-
 5 alty, criminal penalty, or other remedy available to the
 6 Secretary under title XI or title XVIII of the Social Secu-
 7 rity Act for acts prohibited under such titles, including
 8 penalties for false certifications for purposes of receipt of
 9 items or services under the medicare program.

10 (i) AUTHORIZATION OF APPROPRIATIONS.—Pay-
 11 ments for the costs of carrying out the demonstration
 12 project under this section shall be made from the Federal
 13 Supplementary Insurance Trust Fund under section 1841
 14 of such Act (42 U.S.C. 1395t).

15 (j) DEFINITIONS.—In this section:

16 (1) MEDICARE BENEFICIARY.—The term
 17 “medicare beneficiary” means an individual who is
 18 enrolled under part B of title XVIII of the Social
 19 Security Act.

20 (2) HOME HEALTH SERVICES.—The term
 21 “home health services” has the meaning given such
 22 term in section 1861(m) of the Social Security Act
 23 (42 U.S.C. 1395x(m)).

(3) ACTIVITIES OF DAILY LIVING DEFINED.—

The term “activities of daily living” means eating, toileting, transferring, bathing, and dressing.

(4) SECRETARY.—The term “Secretary” means

the Secretary of Health and Human Services.

**SEC. 450A. DEMONSTRATION PROJECT FOR EXCLUSION OF
BRACHYTHERAPY DEVICES FROM PROSPEC-
TIVE PAYMENT SYSTEM FOR OUTPATIENT
HOSPITAL SERVICES.**

(a) DEMONSTRATION PROJECT.—The Secretary shall

conduct a demonstration project under part B of title XVIII of the Social Security Act under which brachytherapy devices shall be excluded from the prospective payment system for outpatient hospital services under the medicare program and, notwithstanding section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)), the amount of payment for a device of brachytherapy furnished under the demonstration project shall be equal to the hospital’s charges for each device furnished, adjusted to cost.

(b) SPECIFICATION OF GROUPS FOR

BRACHYTHERAPY DEVICES.—The Secretary shall create additional groups of covered OPD services that classify devices of brachytherapy furnished under the demonstration project separately from the other services (or group of

1 services) paid for under section 1833(t) of the Social Secu-
 2 rity Act (42 U.S.C. 1395l(t)) in a manner reflecting the
 3 number, isotope, and radioactive intensity of such devices
 4 furnished, including separate groups for palladium-103
 5 and iodine-125 devices.

6 (c) DURATION.—The Secretary shall conduct the
 7 demonstration project under this section for the 3-year pe-
 8 riod beginning on the date that is 90 days after the date
 9 of enactment of this Act.

10 (d) REPORT.—Not later than January 1, 2007, the
 11 Secretary shall submit to Congress a report on the dem-
 12 onstration project conducted under this section. The re-
 13 port shall include an evaluation of patient outcomes under
 14 the demonstration project, as well as an analysis of the
 15 cost effectiveness of the demonstration project.

16 (e) WAIVER AUTHORITY.—The Secretary shall waive
 17 compliance with the requirements of title XVIII of the So-
 18 cial Security Act to such extent and for such period as
 19 the Secretary determines is necessary to conduct the dem-
 20 onstration project under this section.

21 (f) FUNDING.—

22 (1) IN GENERAL.—The Secretary shall provide
 23 for the transfer from the Federal Supplementary In-
 24 surance Trust Fund established under section 1841
 25 of the Social Security Act (42 U.S.C. 1395t) of such

funds as are necessary for the costs of carrying out the demonstration project under this section.

(2) BUDGET NEUTRALITY.—In conducting the demonstration project under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration project under this section was not implemented.

SEC. 450B. REIMBURSEMENT FOR TOTAL BODY ORTHOTIC MANAGEMENT FOR CERTAIN NURSING HOME PATIENTS.

(a) IN GENERAL.—Not later than 60 days after the date of the enactment of this Act, the Secretary shall issue product codes that qualified practioners and suppliers may use to receive reimbursement under section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)) for qualified total body orthotic management devices used for the treatment of nonambulatory individuals with severe musculoskeletal conditions who are in the full-time care of skilled nursing facilities (as defined in section 1861(j) of such Act (42 U.S.C. 1395x(j))). In issuing such codes, the Secretary shall take all steps necessary to prevent fraud and abuse.

1 (b) QUALIFIED TOTAL BODY ORTHOTIC MANAGE-
2 MENT DEVICE.—For purposes of this section, the term
3 “qualified total body orthotic management device” means
4 a medically-prescribed device which—

5 (1) consists of custom fitted individual braces
6 with adjustable points at the hips, knee, ankle,
7 elbow, and wrist, but only if—

8 (A) the individually adjustable braces are
9 attached to a frame which is an integral compo-
10 nent of the device and cannot function or be
11 used apart from the frame; and

12 (B) the frame is designed such that it
13 serves no purpose without the braces; and

14 (2) is designed to—

15 (A) improve function;

16 (B) retard progression of musculoskeletal
17 deformity; or

18 (C) restrict, eliminate, or assist in the
19 functioning of lower and upper extremities and
20 pelvic, spinal, and cervical regions of the body
21 affected by injury, weakness, or deformity,
22 of an individual for whom stabilization of affected
23 areas of the body, or relief of pressure points, is re-
24 quired for medical reasons.

1 **SEC. 450C. AUTHORIZATION OF REIMBURSEMENT FOR ALL**
 2 **MEDICARE PART B SERVICES FURNISHED BY**
 3 **CERTAIN INDIAN HOSPITALS AND CLINICS.**

4 (a) IN GENERAL.—Section 1880(e) (42 U.S.C.
 5 1395qq(e)) is amended—

6 (1) in paragraph (1)(A), by striking “for serv-
 7 ices described in paragraph (2)” and inserting “for
 8 all items and services for which payment may be
 9 made under such part”;

10 (2) by striking paragraph (2); and

11 (3) by redesignating paragraph (3) as para-
 12 graph (2).

13 (b) EFFECTIVE DATE.—The amendments made by
 14 this section shall apply to items and services furnished on
 15 or after October 1, 2004.

16 **SEC. 450D. COVERAGE OF CARDIOVASCULAR SCREENING**
 17 **TESTS.**

18 (a) COVERAGE.—Section 1861(s)(2) of the Social Se-
 19 curity Act (42 U.S.C. 1395x(s)(2)) is amended—

20 (1) in subparagraph (U), by striking “and” at
 21 the end;

22 (2) in subparagraph (V)(iii), by inserting “and”
 23 at the end; and

24 (3) by adding at the end the following new sub-
 25 paragraph:

1 “(W) cardiovascular screening tests (as de-
2 fined in subsection (ww)(1));”.

3 (b) SERVICES DESCRIBED.—Section 1861 of the So-
4 cial Security Act (42 U.S.C. 1395x) is amended by adding
5 at the end the following new subsection:

6 “Cardiovascular Screening Tests

7 “(ww)(1) The term ‘cardiovascular screening tests’
8 means the following diagnostic tests for the early detection
9 of cardiovascular disease:

10 “(A) Tests for the determination of cholesterol
11 levels.

12 “(B) Tests for the determination of lipid levels
13 of the blood.

14 “(C) Such other tests for cardiovascular disease
15 as the Secretary may approve.

16 “(2)(A) Subject to subparagraph (B), the Secretary
17 shall establish standards, in consultation with appropriate
18 organizations, regarding the frequency and type of cardio-
19 vascular screening tests.

20 “(B) With respect to the frequency of cardiovascular
21 screening tests approved by the Secretary under subpara-
22 graph (A), in no case may the frequency of such tests be
23 more often than once every 2 years.”.

24 (c) FREQUENCY.—Section 1862(a)(1) of the Social
25 Security Act (42 U.S.C. 1395y(a)(1)) is amended—

(1) by striking “and” at the end of subparagraph (H);

(2) by striking the semicolon at the end of subparagraph (I) and inserting “, and”; and

(3) by adding at the end the following new subparagraph:

“(J) in the case of a cardiovascular screening test (as defined in section 1861(w)(1)), which is performed more frequently than is covered under section 1861(w)(2).”.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2005.

SEC. 450E. MEDICARE COVERAGE OF SELF-INJECTED BIOLOGICALS.

(a) COVERAGE.—

(1) IN GENERAL.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

(A) in subparagraph (U), by striking “and” at the end;

(B) in subparagraph (V), by inserting “and” at the end; and

(C) by adding at the end the following new subparagraph:

(1) in the last sentence, by inserting “, and before January 1, 2004” after “prior to such date”;

and

(2) by adding at the end the following new sentence: “Effective for items and services furnished on or after January 1, 2004 (with respect to periods beginning on or after June 1, 2002), clauses (i) and (ii) shall be applied by substituting ‘36-month’ for ‘12-month’ each place it appears in the first sentence.

SEC. 450G. REQUIRING THE INTERNAL REVENUE SERVICE

TO DEPOSIT INSTALLMENT AGREEMENT AND

OTHER FEES IN THE TREASURY AS MIS-

CELLANEOUS RECEIPTS.

Notwithstanding any other provision of law, the Secretary of the Treasury is required to deposit in the Treasury as miscellaneous receipts any fee receipts, including fees from installment agreements and restructured installment agreements, collected under the authority provided by Section 3 of the Administrative Provisions of the Internal Revenue Service of Public Law 103-329, the Treasury, Postal Service and General Government Appropriations Act, 1995. Fees collected under this section shall be available for use by the Internal Revenue Service only to

1 the extent that such authority is provided in advance in
 2 an appropriations Act.

3 **SEC. 450H INCREASING TYPES OF ORIGINATING TELE-**
 4 **HEALTH SITES AND FACILITATING THE PRO-**
 5 **VISION OF TELEHEALTH SERVICES ACROSS**
 6 **STATE LINES.**

7 (a) INCREASING TYPES OF ORIGINATING SITES.—

8 Section 1834(m)(4)(C)(ii) (42 U.S.C.
 9 1395m(m)(4)(C)(ii)) is amended by adding at the end the
 10 following new subclauses:

11 “(VI) A skilled nursing facility
 12 (as defined in section 1819(a)).

13 “(VII) An assisted-living facility
 14 (as defined by the Secretary).

15 “(VIII) A board-and-care home
 16 (as defined by the Secretary).

17 “(IX) A county of community
 18 health clinic (as defined by the Sec-
 19 retary).

20 “(X) A community mental health
 21 center (as described in section
 22 1861(ff)(2)(B)).

23 “(XI) A long-term care facility
 24 (as defined by the Secretary).

“(XII) A facility operated by the Indian Health Service or by an Indian tribe, tribal organization, or an urban Indian organization (as such terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)) directly, or under contract or other arrangement.”.

(b) FACILITATING THE PROVISION OF TELEHEALTH SERVICES ACROSS STATE LINES.—

(1) IN GENERAL.—For purposes of expediting the provision of telehealth services for which payment is made under the medicare program under section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), across State lines, the Secretary shall, in consultation with representatives of States, physicians, health care practitioners, and patient advocates, encourage and facilitate the adoption of State provisions allowing for multistate practitioner licensure across State lines.

(2) DEFINITIONS.—In this subsection:

(A) TELEHEALTH SERVICE.—The term “telehealth service” has the meaning given that term in subparagraph (F)(i) of section

1 1834(m)(4) of the Social Security Act (42
2 U.S.C. 1395m(m)(4)).

3 (B) PHYSICIAN, PRACTITIONER.—The
4 terms “physician” and “practitioner” have the
5 meaning given those terms in subparagraphs
6 (D) and (E), respectively, of such section.

7 (C) MEDICARE PROGRAM.—The term
8 “medicare program” means the program of
9 health insurance administered by the Secretary
10 under title XVIII of the Social Security Act (42
11 U.S.C. 1395 et seq.).

12 **SEC. 450I. DEMONSTRATION PROJECT FOR COVERAGE OF**
13 **SURGICAL FIRST ASSISTING SERVICES OF**
14 **CERTIFIED REGISTERED NURSE FIRST AS-**
15 **SISTANTS.**

16 (a) DEMONSTRATION PROJECT.—The Secretary shall
17 conduct a demonstration project under part B of title
18 XVIII of the Social Security Act under which payment is
19 made for surgical first assisting services furnished by a
20 certified registered nurse first assistant to medicare bene-
21 ficiaries.

22 (b) DEFINITIONS.—In this section:

23 (1) SURGICAL FIRST ASSISTING SERVICES.—
24 The term “surgical first assisting services” means
25 services consisting of first assisting a physician with

1 surgery and related preoperative, intraoperative, and
2 postoperative care (as determined by the Secretary)
3 furnished by a certified registered nurse first assist-
4 ant (as defined in paragraph (2)) which the certified
5 registered nurse first assistant is legally authorized
6 to perform by the State in which the services are
7 performed.

8 (2) CERTIFIED REGISTERED NURSE FIRST AS-
9 SISTANT.—The term “certified registered nurse first
10 assistant” means an individual who—

11 (A) is a registered nurse and is licensed to
12 practice nursing in the State in which the surgical
13 first assisting services are performed;

14 (B) has completed a minimum of 2,000 hours
15 of first assisting a physician with surgery and re-
16 lated preoperative, intraoperative, and postoperative
17 care; and

18 (C) is certified as a registered nurse first assist-
19 ant by an organization recognized by the Secretary.

20 (c) PAYMENT RATES.—Payment under the dem-
21 onstration project for surgical first assisting services fur-
22 nished by a certified registered nurse first assistant shall
23 be made at the rate of 80 percent of the lesser of the ac-
24 tual charge for the services or 85 percent of the amount
25 determined under the fee schedule established under sec-

tion 1848(b) of the Social Security Act (42 U.S.C. 1395w-4(b)) for the same services if furnished by a physician.

(d) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in States selected by the Secretary.

(e) DURATION.—The Secretary shall conduct the demonstration project for the 3-year period beginning on the date that is 90 days after the date of the enactment of this Act.

(f) REPORT.—Not later than January 1, 2007, the Secretary shall submit to Congress a report on the project. The report shall include an evaluation of patient outcomes under the project, as well as an analysis of the cost effectiveness of the project.

(g) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Supplementary Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395t) of such funds as are necessary for the costs of carrying out the project under this section.

(2) BUDGET NEUTRALITY.—In conducting the project under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would

have paid if the project under this section was not implemented.

(i) **WAIVER AUTHORITY.**—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

SEC. 450J. EQUITABLE TREATMENT FOR CHILDREN'S HOSPITALS.

(a) **IN GENERAL.**—Section 1833(t)(7)(D)(ii) (42 U.S.C. 1395l(t)(7)(D)(ii)) is amended to read as follows:

“(ii) **PERMANENT TREATMENT FOR CANCER HOSPITALS AND CHILDREN’S HOSPITALS.**—

“(I) **IN GENERAL.**—Subject to subsection (II), in the case of a hospital described in clause (iii) or (v) of section 1886(d)(1)(B), for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

1 “(II) SPECIAL RULE FOR CER-
 2 TAIN CHILDREN’S HOSPITALS.—In the
 3 case of a hospital described in section
 4 1886(d)(1)(B)(iii) that is located in a
 5 State with a reimbursement system
 6 under section 1814(b)(3), but that is
 7 not reimbursed under such system, for
 8 uncovered OPD services furnished on or
 9 after October 1, 2003, and for which
 10 the PPS amount is less than the
 11 greater of the pre-BBA amount or the
 12 reasonable operating and capital costs
 13 without reductions of the hospital in
 14 providing such services, the amount of
 15 payment under this subsection shall
 16 be increased by the amount of such
 17 difference.”.

18 **SEC. 450K. TREATMENT OF PHYSICIANS’ SERVICES FUR-**
 19 **NISHED IN ALASKA.**

20 Section 1848(b) (42 U.S.C. 1395w-4(b)) is amend-
 21 ed—

22 (1) in paragraph (1), in the matter preceding
 23 subparagraph (A), by striking “paragraph (2)” and
 24 inserting “paragraphs (2) and (4)”; and

(2) by adding at the end the following new paragraph:

“(4) TREATMENT OF PHYSICIANS’ SERVICES FURNISHED IN ALASKA.—

“(A) IN GENERAL.—With respect to physicians’ services furnished in Alaska on or after January 1, 2004, and before January 1, 2006, the fee schedule for such services shall be determined as follows:

“(i) Subject to clause (ii), the payment amount for a service furnished in a year shall be an amount equal to—

“(I) in the case of services furnished in calendar year 2004, 90 percent of the VA Alaska fee schedule amount for the service for fiscal year 2001; and

“(II) in the case of services furnished in calendar year 2005, the amount determined under subclause (I) for 2004, increased by the annual update determined under subsection (d) for the year involved.

“(ii) In the case of a service for which there was no VA Alaska fee schedule

1 amount for fiscal year 2001, the payment
2 amount shall be an amount equal to the
3 sum of—

4 “(I) the amount of payment for
5 the service that would otherwise apply
6 under this section; plus

7 “(II) an amount equal to the ap-
8 plicable percent (as described in sub-
9 paragraph (C)) of the amount de-
10 scribed in subclause (I).

11 “(B) VA ALASKA FEE SCHEDULE
12 AMOUNT.—For purposes of this paragraph, the
13 term ‘VA Alaska fee schedule amount’ means
14 the amount that was paid by the Department of
15 Veterans Affairs in Alaska in fiscal year 2001
16 for non-Department of Veterans Affairs physi-
17 cians’ services associated with either outpatient
18 or inpatient care provided to individuals eligible
19 for hospital care or medical services under
20 chapter 17 of title 38, United States Code, at
21 a non-Department facility (as that term is de-
22 fined in section 1701(4) of such title 38.

23 “(C) APPLICABLE PERCENT.—For pur-
24 poses of this paragraph, the term ‘applicable
25 percent’ means the weighted average percentage

(based on claims under this section) by which the fiscal year 2001 VA Alaska fee schedule amount for physicians' services exceeded the amount of payment for such services under this section that applied in Alaska in 2001.".

SEC. 450L. DEMONSTRATION PROJECT TO EXAMINE WHAT WEIGHT LOSS WEIGHT MANAGEMENT SERVICES CAN COST EFFECTIVELY REACH THE SAME RESULT AS THE NIH DIABETES PRIMARY PREVENTION TRIAL STUDY: A 50 PERCENT REDUCTION IN THE RISK FOR TYPE 2 DIABETES FOR INDIVIDUALS WHO HAVE IMPAIRED GLUCOSE TOLERANCE AND ARE OBESE.

(a) IN GENERAL.—Inasmuch as the NIH Diabetes Primary Prevention Trial study proved that the risk of type 2 diabetes could be cut in half when the Institute of Medicine definition of successful weight loss (5 percent weight loss maintained for a year) is achieved by individuals at risk for type 2 diabetes due to obesity and impaired glucose tolerance, the Secretary shall conduct a demonstration project to examine the cost effectiveness and health benefits of providing group weight loss management services to achieve the same result for beneficiaries under the medicare program under title XVIII of the So-

1 cial Security Act who are obese and have impaired glucose
2 tolerance.

3 (b) LIMITATION.—The cost of the group weight loss
4 management services provided under subsection (a) shall
5 not exceed the cost per recipient per year of the medical
6 nutritional therapy benefit currently available to medicare
7 beneficiaries.

8 (c) SCOPE OF SERVICES.—

9 (1) DURATION.—The project shall be conducted
10 for a period of 2 fiscal years.

11 (2) SITES.—The Secretary shall designate the
12 sites at which to conduct the demonstration program
13 under this section. In selecting sites under this para-
14 graph, the Secretary shall give preference to sites lo-
15 cated in—

16 (A) rural areas; or

17 (B) areas that have a high concentration
18 of Native Americans with type 2 diabetes.

19 (3) FUNDING.—

20 (A) IN GENERAL.—Subject to subpara-
21 graph (B), the Secretary shall provide for the
22 transfer from the Federal Supplementary In-
23 surance Trust Fund established under section
24 1841 of such Act (42 U.S.C. 1395t) of such
25 funds as are necessary for the costs of carrying

1 out the demonstration program under this sec-
 2 tion.

3 (B) LIMITATION.—The total amount of the
 4 payments that may be made under this section
 5 shall not exceed \$2,500,000 for each fiscal year
 6 in which the project is conducted under para-
 7 graph (1).

8 (d) COVERAGE AS MEDICARE PART B SERVICES.—

9 (1) IN GENERAL.—Subject to the succeeding
 10 provisions of this subsection, medical nutrition ther-
 11 apy services furnished under the project shall be
 12 considered to be services covered under part B of
 13 title XVIII of the Social Security Act (42 U.S.C.
 14 1395j et seq.).

15 (2) PAYMENT.—Payment for such services shall
 16 be made at a rate of 80 percent of the lesser of the
 17 actual charge for the services or 85 percent of the
 18 fee schedule amount provided under section 1848 of
 19 the Social Security Act (42 U.S.C. 139w-4) for the
 20 same services if such services were furnished by a
 21 physician.

22 (3) APPLICATION OF LIMITS OF BILLING.—The
 23 provisions of section 1842(b)(18) of the Social Secu-
 24 rity Act (42 U.S.C. 1395u(b)(18)) shall apply to a
 25 group weight loss management professional fur-

1 nishing services under the project in the same man-
2 ner as they to a practitioner described in subpara-
3 graph (C) of such section furnishing services under
4 title XVIII of such Act.

5 (e) REPORTS.—The Secretary shall submit to the
6 Committee on Ways and Means and the Committee on
7 Commerce of the House of Representatives and the Com-
8 mittee on Finance of the Senate interim reports on the
9 project and a final report on the project not later than
10 the date that is 6 months after the date on which the
11 project concludes. The final report shall include an evalua-
12 tion of the impact of the use of group weight loss manage-
13 ment services as part of medical nutrition therapy on
14 medicare beneficiaries and on the medicare program, in-
15 cluding any impact on reducing costs under the program
16 and improving the health of beneficiaries. ...

17 (f) DEFINITIONS.—For purposes of this section:

18 (1) The term “obesity” means that an indi-
19 vidual has a Body Mass Index (BMI) of 30 and
20 above.

21 (2) GROUP WEIGHT LOSS MANAGEMENT SERV-
22 ICES.—The term “group weight loss management
23 services” means comprehensive services furnished to
24 individuals who have been diagnosed and referred by

a physician as having impaired glucose tolerance and who are obese that consist of—

(A) assessment and treatment based on the needs of individuals as determined by a group weight loss management professional; or

(B) a specific program or method that has demonstrated its efficacy to produce and maintain weight loss through results published in peer-reviewed scientific journals using recognized research methods and statistical analysis that provides—

(i) assessment of current body weight and recording of weight status at each meeting session;

(ii) provision of a healthy eating plan;

(iii) provision of an activity plan;

(iv) provision of a behavior modification plan; and

(v) a weekly group support meeting.

(3) GROUP WEIGHT LOSS MANAGEMENT PROFESSIONAL.—The term “group weight loss management professional” means an individual who has completed training to provide a program or method that has completed clinical trials and has dem-

onstrated its efficacy through publications in peer-reviewed scientific journals who—

(A)(i) holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) in nutrition social work, psychology with experience in behavioral modification methods to reduce obesity; or

(ii) has completed a curriculum of training for a specific behavioral based weight management program as described in section (4)(A)(2) and recommended in the NIH Clinical Guidelines on Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, chapter 4, section H, parts 1, 2, 3, 4, and pursuant to guidelines by the Secretary; and

(B)(i) is licensed or certified as a group weight loss management professional by the State in which the services are performed; or

(ii) is certified by an organization that meets such criteria as the Secretary establishes

with—

(I) national organizations representing consumers such as the American Obesity Association and the elderly; and

(II) such other organizations as the

Secretary determines appropriate.

Subtitle C—Provisions Relating to Parts A and B

SEC. 451. INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) IN GENERAL.—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) on or after October 1, 2004, and before October 1, 2006, the Secretary shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 5 percent.

(b) WAIVING BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395fff) applicable to home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a).

(c) NO EFFECT ON SUBSEQUENT PERIODS.—The payment increase provided under subsection (a) for a period under such subsection—

(1) shall not apply to episodes and visits ending after such period; and

1 (2) shall not be taken into account in calcu-
 2 lating the payment amounts applicable for episodes
 3 and visits occurring after such period.

4 **SEC. 452. LIMITATION ON REDUCTION IN AREA WAGE AD-**
 5 **JUSTMENT FACTORS UNDER THE PROSPEC-**
 6 **TIVE PAYMENT SYSTEM FOR HOME HEALTH**
 7 **SERVICES.**

8 Section 1895(b)(4)(C) (42 U.S.C. 1395fff(b)(4)(C))
 9 is amended—

10 (1) by striking “FACTORS.—The Secretary” and
 11 inserting “FACTORS.—

12 “(i) IN GENERAL.—Subject to clause
 13 (ii), the Secretary”; and

14 (2) by adding at the end the following new
 15 clause:

16 “(ii) LIMITATION ON REDUCTION IN
 17 FISCAL YEAR 2005 AND 2006.—For fiscal
 18 years 2005 and 2006, the area wage ad-
 19 justment factor applicable to home health
 20 services furnished in an area in the fiscal
 21 year may not be more than 3 percent less
 22 than the area wage adjustment factor ap-
 23 plicable to home health services for the
 24 area for the previous year.”.

1 **SEC. 453. CLARIFICATIONS TO CERTAIN EXCEPTIONS TO**
 2 **MEDICARE LIMITS ON PHYSICIAN REFER-**
 3 **RALS.**

4 (a) **LIMITS ON PHYSICIAN REFERRALS.—**

5 (1) **OWNERSHIP AND INVESTMENT INTERESTS**
 6 **IN WHOLE HOSPITALS.—**

7 (A) **IN GENERAL.—**Section 1877(d)(3) (42
 8 U.S.C. 1395nn(d)(3)) is amended—

9 (i) by striking “and” at the end of
 10 subparagraph (A); and

11 (ii) by redesignating subparagraph
 12 (B) as subparagraph (C) and inserting
 13 after subparagraph (A) the following:

14 “(B) the hospital is not a specialty hospital
 15 (as defined in subsection (h)(7)); and”.

16 (B) **DEFINITION.—**Section 1877(h) (42
 17 U.S.C. 1395nn(h)) is amended by adding at the
 18 end the following:

19 “(7) **SPECIALTY HOSPITAL.—**

20 “(A) **IN GENERAL.—**For purposes of this
 21 section, except as provided in subparagraph
 22 (B), the term ‘specialty hospital’ means a hos-
 23 pital that is primarily or exclusively engaged in
 24 the care and treatment of one of the following:

25 “(i) patients with a cardiac condition;

1 “(ii) patients with an orthopedic con-
2 dition;

3 “(iii) patients receiving a surgical pro-
4 cedure; or

5 “(iv) any other specialized category of
6 patients or cases that the Secretary des-
7 ignates as inconsistent with the purpose of
8 permitting physician ownership and invest-
9 ment interests in a hospital under this sec-
10 tion.

11 “(B) EXCEPTION.—For purposes of this
12 section, the term ‘specialty hospital’ does not
13 include any hospital—

14 “(i) determined by the Secretary—

15 “(I) to be in operation before
16 June 12, 2003; or

17 “(II) under development as of
18 such date;

19 “(ii) for which the number of beds
20 and the number of physician investors at
21 any time on or after such date is no great-
22 er than the number of such beds or inves-
23 tors as of such date; and

24 “(iii) that meets such other require-
25 ments as the Secretary may specify.”.

(2) OWNERSHIP AND INVESTMENT INTERESTS
IN A RURAL PROVIDER.—Section 1877(d)(2) (42
U.S.C. 1395nn(d)(2)) is amended to read as follows:

“(2) RURAL PROVIDERS.—In the case of des-
ignated health services furnished in a rural area (as
defined in section 1886(d)(2)(D)) by an entity, if—

“(A) substantially all of the designated
health services furnished by the entity are fur-
nished to individuals residing in such a rural
area; ~~RANDOMLY SELECTED~~

“(B) the entity is not a specialty hospital
(as defined in subsection (h)(7)); and

“(C) the Secretary determines, with re-
spect to such entity, that such services would
not be available in such area but for the owner-
ship or investment interest.”.

(b) EFFECTIVE DATE.—Subject to paragraph (2),
the amendments made by this section shall apply to refer-
rals made for designated health services on or after Janu-
ary 1, 2004. ~~“REPEALED BY SECTION 1141~~

(c) APPLICATION OF EXCEPTION FOR HOSPITALS
UNDER DEVELOPMENT.—For purposes of section
1877(h)(7)(B)(i)(II) of the Social Security Act, as added
by subsection (a)(1)(B), in determining whether a hospital

1 is under development as of June 12, 2003, the Secretary
2 shall consider—

3 (1) whether architectural plans have been com-
4 pleted, funding has been received, zoning require-
5 ments have been met, and necessary approvals from
6 appropriate State agencies have been received; and

7 (2) any other evidence the Secretary determines
8 would indicate whether a hospital is under develop-
9 ment as of such date.

10 **SEC. 454. DEMONSTRATION PROGRAM FOR SUBSTITUTE**
11 **ADULT DAY SERVICES.**

12 (a) **ESTABLISHMENT.**—The Secretary shall establish
13 a demonstration program (in this section referred to as
14 the “demonstration program”) under which the Secretary
15 provides eligible medicare beneficiaries with coverage
16 under the medicare program of substitute adult day serv-
17 ices furnished by an adult day services facility.

18 (b) **PAYMENT RATE FOR SUBSTITUTE ADULT DAY**
19 **SERVICES.**—

20 (1) **PAYMENT RATE.**—For purposes of making
21 payments to an adult day services facility for sub-
22 stitute adult day services under the demonstration
23 program, the following rules shall apply:

24 (A) **ESTIMATION OF PAYMENT AMOUNT.**—

25 The Secretary shall estimate the amount that

1 would otherwise be payable to a home health
2 agency under section 1895 of the Social Secu-
3 rity Act (42 U.S.C. 1395fff) for all home health
4 services described in subsection (i)(4)(B)(i)
5 under the plan of care.

6 (B) AMOUNT OF PAYMENT.—Subject to
7 paragraph (3)(B), the total amount payable for
8 substitute adult day services under the plan of
9 care is equal to 95 percent of the amount esti-
10 mated to be payable under subparagraph (A).

11 (2) LIMITATION ON BALANCE BILLING.—Under
12 the demonstration program, an adult day services
13 facility shall accept as payment in full for substitute
14 adult day services (including those services described
15 in clauses (ii) through (iv) of subsection (i)(4)(B))
16 furnished by the facility to an eligible medicare ben-
17 eficiary the amount of payment provided under the
18 demonstration program for home health services
19 consisting of substitute adult services.

20 (3) ADJUSTMENT IN CASE OF OVERUTILIZA-
21 TION OF SUBSTITUTE ADULT DAY SERVICES TO EN-
22 SURE BUDGET NEUTRALITY.—The Secretary shall
23 monitor the expenditures under the demonstration
24 program and under title XVIII of the Social Secu-
25 rity Act for home health services. If the Secretary

1 estimates that the total expenditures under the dem-
 2 onstration program and under such title XVIII for
 3 home health services for a period determined by the
 4 Secretary exceed expenditures that would have been
 5 made under such title XVIII for home health serv-
 6 ices for such period if the demonstration program
 7 had not been conducted, the Secretary shall adjust
 8 the rate of payment to adult day services facilities
 9 under paragraph (1)(B) in order to eliminate such
 10 excess.

11 (c) DEMONSTRATION PROGRAM SITES.—The dem-
 12 onstration program shall be conducted in not more than
 13 3 sites selected by the Secretary.

14 (d) DURATION; IMPLEMENTATION.—

15 (1) DURATION.—The Secretary shall conduct
 16 the demonstration program for a period of 3 years.

17 (2) IMPLEMENTATION.—The Secretary may not
 18 implement the demonstration program before Octo-
 19 ber 1, 2004.

20 (e) VOLUNTARY PARTICIPATION.—Participation of
 21 eligible medicare beneficiaries in the demonstration pro-
 22 gram shall be voluntary.

23 (f) WAIVER AUTHORITY.—

24 (1) IN GENERAL.—Except as provided in para-
 25 graph (2), the Secretary may waive such require-

ments of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be necessary for the purposes of carrying out the demonstration program.

(2) MAY NOT WAIVE ELIGIBILITY REQUIREMENTS FOR HOME HEALTH SERVICES.—The Secretary may not waive the beneficiary eligibility requirements for home health services under title XVIII of the Social Security Act.

(g) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall conduct an evaluation of the clinical and cost effectiveness of the demonstration program.

(2) REPORT.—Not later than 30 months after the commencement of the demonstration program, the Secretary shall submit to Congress a report on the evaluation conducted under paragraph (1) and shall include in the report the following:

(A) An analysis of the patient outcomes and costs of furnishing care to the eligible medicare beneficiaries participating in the demonstration program as compared to such outcomes and costs to such beneficiaries receiving only home health services under title XVIII of

1 the Social Security Act for the same health con-
2 ditions.

3 (B) Such recommendations regarding the
4 extension, expansion, or termination of the pro-
5 gram as the Secretary determines appropriate.

6 (i) DEFINITIONS.—In this section:

7 (1) ADULT DAY SERVICES FACILITY.—

8 (A) IN GENERAL.—Except as provided in
9 subparagraphs (B) and (C), the term “adult
10 day services facility” means a public agency or
11 private organization, or a subdivision of such an
12 agency or organization, that—

13 (i) is engaged in providing skilled
14 nursing services and other therapeutic
15 services directly or under arrangement
16 with a home health agency;

17 (ii) provides the items and services de-
18 scribed in paragraph (4)(B); and

19 (iii) meets the requirements of para-
20 graphs (2) through (8) of subsection (o).

21 (B) INCLUSION.—Notwithstanding sub-
22 paragraph (A), the term “adult day services fa-
23 cility” shall include a home health agency in
24 which the items and services described in

1 clauses (ii) through (iv) of paragraph (4)(B)
 2 are provided—

3 (i) by an adult day services program
 4 that is licensed or certified by a State, or
 5 accredited, to furnish such items and serv-
 6 ices in the State; and
 7 (ii) under arrangements with that
 8 program made by such agency.

9 (C) WAIVER OF SURETY BOND.—The Sec-
 10 retary may waive the requirement of a surety
 11 bond under section 1861(o)(7) of the Social Se-
 12 curity Act (42 U.S.C. 1395x(o)(7)) in the case
 13 of an agency or organization that provides a
 14 comparable surety bond under State law.

15 (2) ELIGIBLE MEDICARE BENEFICIARY.—The
 16 term “eligible medicare beneficiary” means an indi-
 17 vidual eligible for home health services under title
 18 XVIII of the Social Security Act.

19 (3) HOME HEALTH AGENCY.—The term “home
 20 health agency” has the meaning given such term in
 21 section 1861(o) of the Social Security Act (42
 22 U.S.C. 1395x(o)).

23 (4) SUBSTITUTE ADULT DAY SERVICES.—

24 (A) IN GENERAL.—The term “substitute
 25 adult day services” means the items and serv-

1 ices described in subparagraph (B) that are fur-
2 nished to an individual by an adult day services
3 facility as a part of a plan under section
4 1861(m) of the Social Security Act (42 U.S.C.
5 1395x(m)) that substitutes such services for
6 some or all of the items and services described
7 in subparagraph (B)(i) furnished by a home
8 health agency under the plan, as determined by
9 the physician establishing the plan.

10 (B) ITEMS AND SERVICES DESCRIBED.—

11 The items and services described in this sub-
12 paragraph are the following items and services:

13 (i) Items and services described in
14 paragraphs (1) through (7) of such section
15 1861(m).

16 (ii) Meals.

17 (iii) A program of supervised activities
18 designed to promote physical and mental
19 health and furnished to the individual by
20 the adult day services facility in a group
21 setting for a period of not fewer than 4
22 and not greater than 12 hours per day.

23 (iv) A medication management pro-
24 gram (as defined in subparagraph (C)).

(C) MEDICATION MANAGEMENT PROGRAM.—For purposes of subparagraph (B)(iv), the term “medication management program” means a program of services, including medicine screening and patient and health care provider education programs, that provides services to minimize—

(i) unnecessary or inappropriate use of prescription drugs; and

(ii) adverse events due to unintended prescription drug-to-drug interactions.

SEC. 455. MEDPAC STUDY ON MEDICARE PAYMENTS AND EFFICIENCIES IN THE HEALTH CARE SYSTEM.

Not later than 18 months after the date of enactment of this Act, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall provide Congress with recommendations to recognize and reward, within payment methodologies for physicians and hospitals established under the medicare program under title XVIII of the Social Security Act, efficiencies, and the lower utilization of services created by the practice of medicine in historically efficient and low-cost areas. Measures of efficiency recognized in accordance with the preceding sentence shall include—

1 (1) shorter hospital stays than the national av-
2 erage;

3 (2) fewer physician visits than the national av-
4 erage;

5 (3) fewer laboratory tests than the national av-
6 erage;

7 (4) a greater utilization of hospice services than
8 the national average; and

9 (5) the efficacy of disease management and pre-
10 ventive health services.

11 **SEC. 456. MEDICARE COVERAGE OF KIDNEY DISEASE EDU-
12 CATION SERVICES.**

13 (a) COVERAGE OF KIDNEY DISEASE EDUCATION
14 SERVICES.—

15 (1) IN GENERAL.—Section 1861 of the Social
16 Security Act (42 U.S.C.1395x) is amended—

17 (A) in subsection (s)(2)—

18 (i) in subparagraph (U), by striking
19 “and” at the end;

20 (ii) in subparagraph (V)(iii), by add-
21 ing “and” at the end; and

22 (iii) by adding at the end the fol-
23 lowing new subparagraph:

24 “(W) kidney disease education services (as de-
25 fined in subsection (ww));”; and

(B) by adding at the end the following new subsection:

“Kidney Disease Education Services

“(ww)(1) The term ‘kidney disease education services’ means educational services that are—

“(A) furnished to an individual with kidney disease who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant;

“(B) furnished, upon the referral of the physician managing the individual’s kidney condition, by a qualified person (as defined in paragraph (2)); and

“(C) designed—

“(i) to provide comprehensive information regarding—

“(I) the management of comorbidities;

“(II) the prevention of uremic complications; and

“(III) each option for renal replacement therapy (including peritoneal dialysis, hemodialysis (including vascular access options), and transplantation); and

“(ii) to ensure that the individual has the opportunity to actively participate in the choice of therapy.

1 “(2) The term ‘qualified person’ means—

2 “(A) a physician (as described in subsection
3 (r)(1));

4 “(B) an individual who—

5 “(i) is—

6 “(I) a registered nurse;

7 “(II) a registered dietitian or nutri-
8 tion professional (as defined in subsection
9 (vv)(2));

10 “(III) a clinical social worker (as de-
11 fined in subsection (hh)(1));

12 “(IV) a physician assistant, nurse
13 practitioner, or clinical nurse specialist (as
14 those terms are defined in subsection
15 (aa)(5)); or

16 “(V) a transplant coordinator; and

17 “(ii) meets such requirements related to
18 experience and other qualifications that the
19 Secretary finds necessary and appropriate for
20 furnishing the services described in paragraph
21 (1); or

22 “(C) a renal dialysis facility subject to the re-
23 quirements of section 1881(b)(1) with personnel
24 who—

“(i) provide the services described in paragraph (1); and

“(ii) meet the requirements of subparagraph (A) or (B).”

“(3) The Secretary shall develop the requirements under paragraph (2)(B)(ii) after consulting with physicians, health educators, professional organizations, accrediting organizations, kidney patient organizations, dialysis facilities, transplant centers, network organizations described in section 1881(c)(2), and other knowledgeable persons.

“(4) In promulgating regulations to carry out this subsection, the Secretary shall ensure that such regulations ensure that each beneficiary who is entitled to kidney disease education services under this title receives such services in a timely manner that ensures that the beneficiary receives the maximum benefit of those services.

“(5) The Secretary shall monitor the implementation of this subsection to ensure that beneficiaries who are eligible for kidney disease education services receive such services in the manner described in paragraph (4).”

(2) PAYMENT UNDER PHYSICIAN FEE SCHEDULE.—Section 1848(j)(3) of such Act (42 U.S.C. 1395w-4(j)(3)) is amended by inserting “, (2)(W)”, after “(2)(S)”.

1 (3) PAYMENT TO RENAL DIALYSIS FACILI-
2 TIES.—Section 1881(b) of such Act (42 U.S.C.
3 1395rr(b)), as amended by section 433(b)(5), is fur-
4 ther amended by adding at the end the following
5 new paragraph:

6 “(13) For purposes of paragraph (7), the single
7 composite weighted formulas determined under such
8 paragraph shall not take into account the amount of
9 payment for kidney disease education services (as
10 defined in section 1861(w)). Instead, payment for
11 such services shall be made to the renal dialysis fa-
12 cility on an assignment-related basis under section
13 1848.”.

14 (4) ANNUAL REPORT TO CONGRESS.—Not later
15 than April 1, 2004, and annually thereafter, the
16 Secretary of Health and Human Services shall sub-
17 mit to Congress a report on the number of medicare
18 beneficiaries who are entitled to kidney disease edu-
19 cation services (as defined in section 1861(w)) of
20 the Social Security Act, as added by paragraph (1))
21 under title XVIII of such Act and who receive such
22 services, together with such recommendations for
23 legislative and administrative action as the Secretary
24 determines to be appropriate to fulfill the legislative

1 intent that resulted in the enactment of that sub-
2 section.

3 (b) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to services furnished on or after
5 January 1, 2004.

6 **SEC. 457. FRONTIER EXTENDED STAY CLINIC DEMONSTRA-**
7 **TION PROJECT.**

8 (a) AUTHORITY TO CONDUCT DEMONSTRATION
9 PROJECT.—The Secretary shall waive such provisions of
10 the medicare program established under title XVIII of the
11 Social Security Act (42 U.S.C. 1395 et seq.) as are nec-
12 essary to conduct a demonstration project under which
13 frontier extended stay clinics described in subsection (b)
14 in isolated rural areas are treated as providers of items
15 and services under the medicare program.

16 (b) CLINICS DESCRIBED.—A frontier extended stay
17 clinic is described in this subsection if the clinic—

18 (1) is located in a community where the closest
19 short-term acute care hospital or critical access hos-
20 pital is at least 75 miles away from the community
21 or is inaccessible by public road; and

22 (2) is designed to address the needs of—

23 (A) seriously or critically ill or injured pa-
24 tients who, due to adverse weather conditions or

1 other reasons, cannot be transferred quickly to
2 acute care referral centers; or

3 (B) patients who need monitoring and ob-
4 servation for a limited period of time.

5 (c) DEFINITIONS.—In this section, the terms “hos-
6 pital” and “critical access hospital” have the meanings
7 given such terms in subsections (e) and (mm), respec-
8 tively, of section 1861 of the Social Security Act (42
9 U.S.C. 1395x).

10 **SEC. 458. IMPROVEMENTS IN NATIONAL COVERAGE DETER-**
11 **MINATION PROCESS TO RESPOND TO**
12 **CHANGES IN TECHNOLOGY.**

13 (a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y)
14 is amended—

15 (A) in the third sentence of subsection (a)
16 by inserting “consistent with subsection (j)”
17 after “the Secretary shall ensure”; and

18 (B) by adding at the end the following new
19 subsection:

20 “(j) NATIONAL COVERAGE DETERMINATION PROC-
21 ESS.—

22 “(1) TIMEFRAME FOR DECISIONS ON REQUESTS
23 FOR NATIONAL COVERAGE DETERMINATIONS.—In
24 the case of a request for a national coverage deter-
25 mination that—

“(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

“(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

“(2) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—At the end of the 6-month period (with respect to a request under paragraph (1)(A)) or 9-month period (with respect to a request under paragraph (1)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall—

“(A) make a draft of proposed decision on the request available to the public through the Medicare Internet site of the Department of Health and Human Services or other appropriate means;

“(B) provide a 30-day period for public comment on such draft;

1 “(C) make a final decision on the request
 2 within 60 days of the conclusion of the 30-day
 3 period referred to under subparagraph (B);

4 “(D) include in such final decision sum-
 5 maries of the public comments received and re-
 6 sponses thereto;

7 “(E) make available to the public the clin-
 8 ical evidence and other data used in making
 9 such a decision when the decision differs from
 10 the recommendations of the Medicare Coverage
 11 Advisory Committee; and

12 “(F) in the case of a decision to grant the
 13 coverage determination, assign a temporary or
 14 permanent code and implement the coverage de-
 15 cision at the end of the 60-day period referred
 16 to in subparagraph (C).

17 “(3) NATIONAL COVERAGE DETERMINATION
 18 DEFINED.—For purposes of this subsection, the
 19 term ‘national coverage determination’ has the
 20 meaning given such term in section 1869(f)(1)(B).”.

21 (b) EFFECTIVE DATE.—The amendments made by
 22 this section shall apply to national coverage determina-
 23 tions as of January 1, 2004.

1 **SEC. 459. INCREASE IN MEDICARE PAYMENT FOR CERTAIN**
 2 **HOME HEALTH SERVICES.**

3 (a) IN GENERAL.—Section 1895 of the Social Secu-
 4 rity Act (42 U.S.C. 1395fff) is amended by adding at the
 5 end the following:

6 “(f) INCREASE IN PAYMENT FOR SERVICES FUR-
 7 NISHED IN A RURAL AREA.—

8 “(1) IN GENERAL.—In the case of home health
 9 services furnished in a rural area (as defined in sec-
 10 tion 1886(d)(2)(D)) on or after October 1, 2004 and
 11 before October 1, 2006, the Secretary shall increase
 12 the payment amount otherwise made under this sec-
 13 tion for such services by 10 percent.

14 “(2) WAIVER OF BUDGET NEUTRALITY.—The
 15 Secretary shall not reduce the standard prospective
 16 payment amount (or amounts) under this section ap-
 17 plicable to home health services furnished during
 18 any period to offset the increase in payments result-
 19 ing from the application of paragraph (1).”

20 (b) PAYMENT ADJUSTMENT.—Section 1895(b)(5) of
 21 the Social Security Act (42 U.S.C. 1395fff(b)(5)) is
 22 amended by adding at the end the following: “Notwith-
 23 standing this paragraph, the total amount of the addi-
 24 tional payments or payment adjustments made under this
 25 paragraph may not exceed, with respect to fiscal year
 26 2004, 3 percent, and, with respect to fiscal years 2005

1 and 2006, 4 percent, of the total payments projected or
 2 estimated to be made based on the prospective payment
 3 system under this subsection in the year involved.”.

4 (c) EFFECTIVE DATE.—The amendments made by
 5 this section shall apply to services furnished on or after
 6 October 1, 2003.

7 **SEC. 460. FRONTIER EXTENDED STAY CLINIC DEMONSTRATION PROJECT.**
 8

9 (a) AUTHORITY TO CONDUCT DEMONSTRATION
 10 PROJECT.—The Secretary shall waive such provisions of
 11 the medicare program established under title XVIII of the
 12 Social Security Act (42 U.S.C. 1395 et seq.) as are nec-
 13 essary to conduct a demonstration project under which
 14 frontier extended stay clinics described in subsection (b)
 15 in isolated rural areas are treated as providers of items
 16 and services under the medicare program.

17 (b) CLINICS DESCRIBED.—A frontier extended stay
 18 clinic is described in this subsection if the clinic—

19 (1) is located in a community where the closest
 20 short-term acute care hospital or critical access hos-
 21 pital is at least 75 miles away from the community
 22 or is inaccessible by public road; and

23 (2) is designed to address the needs of—

24 (A) seriously or critically ill or injured pa-
 25 tients who, due to adverse weather conditions or

other reasons, cannot be transferred quickly to acute care referral centers; or

(B) patients who need monitoring and observation for a limited period of time.

(c) DEFINITIONS.—In this section, the terms “hospital” and “critical access hospital” have the meanings given such terms in subsections (e) and (mm), respectively, of section 1861 of the Social Security Act (42 U.S.C. 1395x).

SEC. 461. MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) TECHNICAL AMENDMENT CONCERNING SECRETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—

(1) IN GENERAL.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—

(A) in subparagraph (A)(ii), by striking “promptly (as determined in accordance with regulations)”;

(B) in subparagraph (B)—

(i) by redesignating clauses (i) through (iii) as clauses (ii) through (iv), respectively; and

1 inserted after (ii) by inserting before clause (ii), as
2 so redesignated, the following new clause:

3 “(i) AUTHORITY TO MAKE CONDI-
4 TIONAL PAYMENT.—The Secretary may
5 make payment under this title with respect
6 to an item or service if a primary plan de-
7 scribed in subparagraph (A)(ii) has not
8 made or cannot reasonably be expected to
9 make payment with respect to such item or
10 service promptly (as determined in accord-
11 ance with regulations). Any such payment
12 by the Secretary shall be conditioned on
13 reimbursement to the appropriate Trust
14 Fund in accordance with the succeeding
15 provisions of this subsection.”.

16 (2) EFFECTIVE DATE.—The amendments made
17 by paragraph (1) shall be effective as if included in
18 the enactment of title III of the Medicare and Med-
19 icaid Budget Reconciliation Amendments of 1984
20 (Public Law 98-369).

21 (b) CLARIFYING AMENDMENTS TO CONDITIONAL
22 PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C.
23 1395y(b)(2)) is further amended—

24 (1) in subparagraph (A), in the matter fol-
25 lowing clause (ii), by inserting the following sentence

1 at the end: "An entity that engages in a business,
 2 trade, or profession shall be deemed to have a self-
 3 insured plan if it carries its own risk (whether by a
 4 failure to obtain insurance, or otherwise) in whole or
 5 in part.";

6 (2) in subparagraph (B)(ii), as redesignated by
 7 subsection (a)(2)(B)—

8 (A) by striking the first sentence and in-
 9 serting the following: "A primary plan, and an
 10 entity that receives payment from a primary
 11 plan, shall reimburse the appropriate Trust
 12 Fund for any payment made by the Secretary
 13 under this title with respect to an item or serv-
 14 ice if it is demonstrated that such primary plan
 15 has or had a responsibility to make payment
 16 with respect to such item or service. A primary
 17 plan's responsibility for such payment may be
 18 demonstrated by a judgment, a payment condi-
 19 tioned upon the recipient's compromise, waiver,
 20 or release (whether or not there is a determina-
 21 tion or admission of liability) of payment for
 22 items or services included in a claim against the
 23 primary plan or the primary plan's insured, or
 24 by other means."; and

1 (B) in the final sentence, by striking “on
2 the date such notice or other information is re-
3 ceived” and inserting “on the date notice of, or
4 information related to, a primary plan’s respon-
5 sibility for such payment or other information is
6 received”; and

7 (3) in subparagraph (B)(iii), , as redesignated
8 by subsection (a)(2)(B), by striking the first sen-
9 tence and inserting the following: “In order to re-
10 cover payment made under this title for an item or
11 service, the United States may bring an action
12 against any or all entities that are or were required
13 or responsible (directly, as an insurer or self-insurer,
14 as a third-party administrator, as an employer that
15 sponsors or contributes to a group health plan, or
16 large group health plan, or otherwise) to make pay-
17 ment with respect to the same item or service (or
18 any portion thereof) under a primary plan. The
19 United States may, in accordance with paragraph
20 (3)(A) collect double damages against any such enti-
21 ty. In addition, the United States may recover under
22 this clause from any entity that has received pay-
23 ment from a primary plan or from the proceeds of
24 a primary plan’s payment to any entity.”.

1 (c) CLERICAL AMENDMENTS.—Section 1862(b) (42
2 U.S.C. 1395y(b)) is amended—

3 (1) in paragraph (1)(A), by moving the indenta-
4 tion of clauses (ii) through (v) 2 ems to the left; and

5 (2) in paragraph (3)(A), by striking “such” be-
6 fore “paragraphs”.

7 **SEC. 462. MEDICARE PANCREATIC ISLET CELL TRANS-**
8 **PLANT DEMONSTRATION PROJECT.**

9 (a) ESTABLISHMENT.—In order to test the appro-
10 priateness of pancreatic islet cell transplantation, not later
11 than 120 days after the date of the enactment of this Act,
12 the Secretary shall establish a demonstration project
13 which the Secretary, provides for payment under the medi-
14 care program under title XVIII of the Social Security Act
15 for pancreatic islet cell transplantation and related items
16 and services in the case of medicare beneficiaries who have
17 type I (juvenile) diabetes and have end stage renal disease.

18 (b) DURATION OF PROJECT.—The authority of the
19 Secretary to conduct the demonstration project under this
20 section shall terminate on the date that is 5 years after
21 the date of the establishment of the project.

22 (c) EVALUATION AND REPORT.—The Secretary shall
23 conduct an evaluation of the outcomes of the demonstra-
24 tion project. Not later than 120 days after the date of
25 the termination of the demonstration project under sub-

1 section (b), the Secretary shall submit to Congress a re-
 2 port on the project, including recommendations for such
 3 legislative and administrative action as the Secretary
 4 deems appropriate.

5 (d) PAYMENT METHODOLOGY.—The Secretary shall
 6 establish an appropriate payment methodology for the pro-
 7 vision of items and services under the demonstration
 8 project, which may include a payment methodology that
 9 bundles, to the maximum extent feasible, payment for all
 10 such items and services.

11 **SEC. 463. INCREASE IN MEDICARE PAYMENT FOR CERTAIN**
 12 **HOME HEALTH SERVICES.**

13 (a) IN GENERAL.—Section 1895 of the Social Secu-
 14 rity Act (42 U.S.C. 1395fff) is amended by adding at the
 15 end the following:

16 “(f) INCREASE IN PAYMENT FOR SERVICES FUR-
 17 NISHED IN A RURAL AREA.—

18 “(1) IN GENERAL.—In the case of home health
 19 services furnished in a rural area (as defined in sec-
 20 tion 1886(d)(2)(D)) on or after October 1, 2004,
 21 and before October 1, 2006, the Secretary shall in-
 22 crease the payment amount otherwise made under
 23 this section for such services by 10 percent.

24 “(2) WAIVER OF BUDGET NEUTRALITY.—The
 25 Secretary shall not reduce the standard prospective

payment amount (or amounts) under this section applicable to home health services furnished during any period to offset the increase in payments resulting from the application of paragraph (1).”.

(b) PAYMENT ADJUSTMENT.—Section 1895(b)(5) of the Social Security Act (42 U.S. C. 1395fff(b)(5)) is amended by adding at the end the following: “Notwithstanding this paragraph, the total amount of the additional payments or payment adjustments made under this paragraph may not exceed, with respect to fiscal year 2004, 3 percent, and, with respect to fiscal years 2005 and 2006, 4 percent, of the total payments projected or estimated to be made based on the prospective payment system under this subsection in the year involved.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after October 1, 2003.

**SEC. 464. SENSE OF THE SENATE CONCERNING MEDICARE
PAYMENT UPDATE FOR PHYSICIANS AND
OTHER HEALTH PROFESSIONALS.**

(a) FINDINGS.—The Senate makes the following findings:

(1) The formula by which medicare payments are updated each year for services furnished by phy-

1 sicians and other health professionals is fundamen-
2 tally flawed.

3 (2) The flawed physician payment update for-
4 mula is causing a continuing physician payment cri-
5 sis, and, without congressional action, medicare pay-
6 ment rates for physicians and other practitioners are
7 predicted to fall by 4.2 percent in 2004.

8 (3) A physician payment cut in 2004 would be the
9 fifth cut since 1991, and would be on top of a 5.4
10 percent cut in 2002, with additional cuts estimated
11 for 2005, 2006, and 2007. From 1991 through
12 2003, payment rates for physicians and health pro-
13 fessionals fell 14 percent behind practice cost infla-
14 tion as measured by medicare's own conservative es-
15 timates.

16 (4) The sustainable growth rate (SGR) expendi-
17 ture target, which is the basis for the physician pay-
18 ment update, is linked to the gross domestic product
19 and penalizes physicians and other practitioners for
20 volume increases that they cannot control and that
21 the government actively promotes through new cov-
22 erage decisions, quality improvement activities, and
23 other initiatives that, while beneficial to patients, are
24 not reflected in the SGR.

1 (b) SENSE OF THE SENATE.—It is the sense of the
 2 Senate that medicare beneficiary access to quality care
 3 may be compromised if Congress does not take action to
 4 prevent cuts in 2004 and the following years that result
 5 from the SGR formula.

6 **TITLE V—MEDICARE APPEALS,**
 7 **REGULATORY, AND CON-**
 8 **TRACTING IMPROVEMENTS**
 9 **Subtitle A—Regulatory Reform**

10 **SEC. 501. RULES FOR THE PUBLICATION OF A FINAL REGU-**
 11 **LATION BASED ON THE PREVIOUS PUBLICA-**
 12 **TION OF AN INTERIM FINAL REGULATION.**

13 (a) IN GENERAL.—Section 1871(a) (42 U.S.C.
 14 1395hh(a)) is amended by adding at the end the following
 15 new paragraph:

16 “(3)(A) With respect to the publication of a final reg-
 17 ulation based on the previous publication of an interim
 18 final regulation—

19 “(i) subject to subparagraph (B), the Secretary
 20 shall publish the final regulation within the 12-
 21 month period that begins on the date of publication
 22 of the interim final regulation;

23 “(ii) if a final regulation is not published by the
 24 deadline established under this paragraph, the in-
 25 terim final regulation shall not continue in effect un-

1 less the Secretary publishes a notice described in
 2 subparagraph (B) by such deadline; and

3 “(iii) the final regulation shall include responses
 4 to comments submitted in response to the interim
 5 final regulation.

6 “(B) If the Secretary determines before the deadline
 7 otherwise established in this paragraph that there is good
 8 cause, specified in a notice published before such deadline,
 9 for delaying the deadline otherwise applicable under this
 10 paragraph, the deadline otherwise established under this
 11 paragraph shall be extended for such period (not to exceed
 12 12 months) as the Secretary specifies in such notice.”.

13 (b) EFFECTIVE DATE.—The amendment made by
 14 subsection (a) shall take effect on the date of enactment
 15 of this Act and shall apply to interim final regulations
 16 published on or after such date.

17 (c) STATUS OF PENDING INTERIM FINAL REGULA-
 18 TIONS.—Not later than 6 months after the date of enact-
 19 ment of this Act, the Secretary shall publish a notice in
 20 the Federal Register that provides the status of each in-
 21 terim final regulation that was published on or before the
 22 date of enactment of this Act and for which no final regu-
 23 lation has been published. Such notice shall include the
 24 date by which the Secretary plans to publish the final reg-
 25 ulation that is based on the interim final regulation.

1 **SEC. 502. COMPLIANCE WITH CHANGES IN REGULATIONS**
 2 **AND POLICIES.** *compliance with*

3 (a) NO RETROACTIVE APPLICATION OF SUB-
 4 STANTIVE CHANGES.—

5 (1) IN GENERAL.—Section 1871 (42 U.S.C.
 6 1395hh) is amended by adding at the end the fol-
 7 lowing new subsection:

8 “(d)(1)(A) A substantive change in regulations, man-
 9 ual instructions, interpretative rules, statements of policy,
 10 or guidelines of general applicability under this title shall
 11 not be applied (by extrapolation or otherwise) retroactively
 12 to items and services furnished before the effective date
 13 of the change, unless the Secretary determines that—

14 “(i) such retroactive application is necessary to
 15 comply with statutory requirements; or

16 “(ii) failure to apply the change retroactively
 17 would be contrary to the public interest.”. *from*

18 (2) EFFECTIVE DATE.—The amendment made
 19 by paragraph (1) shall apply to substantive changes
 20 issued on or after the date of enactment of this Act.

21 (b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE
 22 CHANGES AFTER NOTICE.— *for*

23 (1) IN GENERAL.—Section 1871(d)(1), as
 24 added by subsection (a), is amended by adding at
 25 the end the following:

1 “(B) A compliance action may be made against a pro-
2 vider of services, physician, practitioner, or other supplier
3 with respect to noncompliance with such a substantive
4 change only for items and services furnished on or after
5 the effective date of the change.

6 “(C)(i) Except as provided in clause (ii), a sub-
7 stantive change may not take effect before the date that
8 is the end of the 30-day period that begins on the date
9 that the Secretary has issued or published, as the case
10 may be, the substantive change.

11 “(ii) The Secretary may provide for a substantive
12 change to take effect on a date that precedes the end of
13 the 30-day period under clause (i) if the Secretary finds
14 that waiver of such 30-day period is necessary to comply
15 with statutory requirements or that the application of such
16 30-day period is contrary to the public interest. If the Sec-
17 retary provides for an earlier effective date pursuant to
18 this clause, the Secretary shall include in the issuance or
19 publication of the substantive change a finding described
20 in the first sentence, and a brief statement of the reasons
21 for such finding.”.

22 (2) EFFECTIVE DATE.—The amendment made
23 by paragraph (1) shall apply to compliance actions
24 undertaken on or after the date of enactment of this
25 Act.

1 **SEC. 503. REPORT ON LEGAL AND REGULATORY INCON-**
 2 **SISTENCIES.**

3 Section 1871 (42 U.S.C. 1395hh), as amended by
 4 section 502(a)(1), is amended by adding at the end the
 5 following new subsection:

6 “(e)(1) Not later than 2 years after the date of enact-
 7 ment of this subsection, and every 3 years thereafter, the
 8 Secretary shall submit to Congress a report with respect
 9 to the administration of this title and areas of inconsist-
 10 ency or conflict among the various provisions under law
 11 and regulation.

12 “(2) In preparing a report under paragraph (1), the
 13 Secretary shall collect—

14 “(A) information from beneficiaries, providers
 15 of services, physicians, practitioners, and other sup-
 16 pliers with respect to such areas of inconsistency
 17 and conflict; and

18 “(B) information from medicare contractors
 19 that tracks the nature of all communications and
 20 correspondence.

21 “(3) A report under paragraph (1) shall include a de-
 22 scription of efforts by the Secretary to reduce such incon-
 23 sistency or conflicts, and recommendations for legislation
 24 or administrative action that the Secretary determines ap-
 25 propriate to further reduce such inconsistency or con-
 26 flicts.”.

1 **SEC. 504. STREAMLINING AND SIMPLIFICATION OF MEDI-**
 2 **CARE REGULATIONS.**

3 (a) IN GENERAL.—The Secretary of Health and
 4 Human Services shall conduct an analysis of the regula-
 5 tions issued under title XVIII of the Social Security Act
 6 and related laws in order to determine how such regula-
 7 tions may be streamlined and simplified to increase the
 8 efficiency and effectiveness of the medicare program with-
 9 out harming beneficiaries or providers and to decrease the
 10 burdens the medicare payment systems impose on both
 11 beneficiaries and providers.

12 (b) REDUCTION IN REGULATIONS.—The Secretary,
 13 after completion of the analysis under subsection (a), shall
 14 direct the rewriting of the regulations described in sub-
 15 section (a) in such a manner as to—

16 (1) reduce the number of words comprising all
 17 regulations by at least two-thirds by October 1,
 18 2004, and

19 (2) ensure the simple, effective, and efficient
 20 operation of the medicare program.

21 (c) APPLICATION OF THE PAPERWORK REDUCTION
 22 ACT.—The Secretary shall apply the provisions of chapter
 23 35 of title 44, United States Code (commonly known as
 24 the “Paperwork Reduction Act”) to the provisions of this
 25 Act to ensure that any regulations issued to implement
 26 this Act are written in plain language, are streamlined,

1 promote the maximum efficiency and effectiveness of the
 2 medicare and medicaid programs without harming bene-
 3 ficiaries or providers, and minimize the burdens the pay-
 4 ment systems affected by this Act impose on both bene-
 5 ficiaries and providers.

6 (d) FEASIBILITY.—If the Secretary determines that
 7 the two-thirds reduction in words by October 1, 2004 re-
 8 quired in subsection (b)(1) is not feasible, he shall inform
 9 Congress in writing by July 1, 2004 of the reasons for
 10 its unfeasibility. He shall then establish a feasible reduc-
 11 tion to be achieved by January 1, 2005.

12 **Subtitle B—Appeals Process**

13 **Reform**

14 **SEC. 511. SUBMISSION OF PLAN FOR TRANSFER OF RE-**

15 **SPONSIBILITY FOR MEDICARE APPEALS.**

16 (a) SUBMISSION OF TRANSITION PLAN.—

17 (1) IN GENERAL.—Not later than April 1,
 18 2004, the Commissioner of Social Security and the
 19 Secretary shall develop and transmit to Congress
 20 and the Comptroller General of the United States a
 21 plan under which the functions of administrative law
 22 judges responsible for hearing cases under title
 23 XVIII of the Social Security Act (and related provi-
 24 sions in title XI of such Act) are transferred from
 25 the responsibility of the Commissioner and the So-

1 cial Security Administration to the Secretary and
 2 the Department of Health and Human Services.

3 (2) CONTENTS.—The plan shall include infor-
 4 mation on the following:

5 (A) WORKLOAD.—The number of such ad-
 6 ministrative law judges and support staff re-
 7 quired now and in the future to hear and decide
 8 such cases in a timely manner, taking into ac-
 9 count the current and anticipated claims vol-
 10 ume, appeals, number of beneficiaries, and stat-
 11 utory changes.

12 (B) COST PROJECTIONS AND FINANC-
 13 ING.—Funding levels required for fiscal year
 14 2005 and subsequent fiscal years to carry out
 15 the functions transferred under the plan and
 16 how such transfer should be financed.

17 (C) TRANSITION TIMETABLE.—A timetable
 18 for the transition.

19 (D) REGULATIONS.—The establishment of
 20 specific regulations to govern the appeals proc-
 21 ess.

22 (E) CASE TRACKING.—The development of
 23 a unified case tracking system that will facili-
 24 tate the maintenance and transfer of case spe-
 25 cific data across both the fee-for-service and

1 managed care components of the medicare pro-
 2 gram.

3 (F) FEASIBILITY OF PRECEDENTIAL AU-
 4 THORITY.—The feasibility of developing a proc-
 5 ess to give decisions of the Departmental Ap-
 6 peals Board in the Department of Health and
 7 Human Services addressing broad legal issues
 8 binding, precedential authority.

9 (G) ACCESS TO ADMINISTRATIVE LAW
 10 JUDGES.—The feasibility of—

11 (i) filing appeals with administrative
 12 law judges electronically; and

13 (ii) conducting hearings using tele- or
 14 video-conference technologies.

15 (H) INDEPENDENCE OF ADMINISTRATIVE
 16 LAW JUDGES.—The steps that should be taken
 17 to ensure the independence of administrative
 18 law judges, including ensuring that such judges
 19 are in an office that is functionally and oper-
 20 ationally separate from the Centers for Medi-
 21 care & Medicaid Services and the Center for
 22 Medicare Choices.

23 (I) GEOGRAPHIC DISTRIBUTION.—The
 24 steps that should be taken to provide for an ap-
 25 propriate geographic distribution of administra-

1 tive law judges throughout the United States to
2 ensure timely access to such judges.

3 (J) HIRING.—The steps that should be
4 taken to hire administrative law judges (and
5 support staff).

6 (K) PERFORMANCE STANDARDS.—The es-
7 tablishment of performance standards for ad-
8 ministrative law judges with respect to timelines
9 for decisions in cases under title XVIII of the
10 Social Security Act.

11 (L) SHARED RESOURCES.—The feasibility
12 of the Secretary entering into such arrange-
13 ments with the Commissioner of Social Security
14 as may be appropriate with respect to trans-
15 ferred functions under the plan to share office
16 space, support staff, and other resources, with
17 appropriate reimbursement.

18 (M) TRAINING.—The training that should
19 be provided to administrative law judges with
20 respect to laws and regulations under title
21 XVIII of the Social Security Act.

22 (3) ADDITIONAL INFORMATION.—The plan may
23 also include recommendations for further congres-
24 sional action, including modifications to the require-
25 ments and deadlines established under section 1869

of the Social Security Act (as amended by sections 521 and 522 of BIPA (114 Stat. 2763A-534) and this Act).

(b) GAO EVALUATION.—The Comptroller General of the United States shall—

(1) evaluate the plan submitted under subsection (a); and

(2) not later than 6 months after such submission, submit to Congress, the Commissioner of Social Security, and the Secretary a report on such evaluation.

(c) SUBMISSION OF GAO REPORT REQUIRED BEFORE PLAN IMPLEMENTATION.—The Commissioner of Social Security and the Secretary may not implement the plan developed under subsection (a) before the date that is 6 months after the date the report required under subsection (b)(2) is submitted to the Commissioner and the Secretary.

SEC. 512. EXPEDITED ACCESS TO JUDICIAL REVIEW.

(a) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)) is amended—

(1) in paragraph (1)(A), by inserting “, subject to paragraph (2),” before “to judicial review of the Secretary’s final decision”; and

1 (2) by adding at the end the following new
2 paragraph:

3 “(2) EXPEDITED ACCESS TO JUDICIAL RE-
4 VIEW.—

5 “(A) IN GENERAL.—The Secretary shall
6 establish a process under which a provider of
7 services or supplier that furnishes an item or
8 service or a beneficiary who has filed an appeal
9 under paragraph (1) (other than an appeal filed
10 under paragraph (1)(F)(i)) may obtain access
11 to judicial review when a review entity (de-
12 scribed in subparagraph (D)), on its own mo-
13 tion or at the request of the appellant, deter-
14 mines that the Departmental Appeals Board
15 does not have the authority to decide the ques-
16 tion of law or regulation relevant to the matters
17 in controversy and that there is no material
18 issue of fact in dispute. The appellant may
19 make such request only once with respect to a
20 question of law or regulation for a specific mat-
21 ter in dispute in a case of an appeal.

22 “(B) PROMPT DETERMINATIONS.—If, after
23 or coincident with appropriately filing a request
24 for an administrative hearing, the appellant re-
25 quests a determination by the appropriate re-

view entity that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute, and if such request is accompanied by the documents and materials as the appropriate review entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity shall be considered a final decision and not subject to review by the Secretary.

“(C) ACCESS TO JUDICIAL REVIEW.—

“(i) IN GENERAL.—If the appropriate review entity—

“(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have authority to decide; or

1 “(II) fails to make such deter-
 2 mination within the period provided
 3 under subparagraph (B);
 4 then the appellant may bring a civil action
 5 as described in this subparagraph.

6 “(ii) DEADLINE FOR FILING.—Such
 7 action shall be filed, in the case described
 8 in—

9 “(I) clause (i)(I), within 60 days
 10 of the date of the determination de-
 11 scribed in such clause; or

12 “(II) clause (i)(II), within 60
 13 days of the end of the period provided
 14 under subparagraph (B) for the deter-
 15 mination.

16 “(iii) VENUE.—Such action shall be
 17 brought in the district court of the United
 18 States for the judicial district in which the
 19 appellant is located (or, in the case of an
 20 action brought jointly by more than 1 ap-
 21 plicant, the judicial district in which the
 22 greatest number of applicants are located)
 23 or in the District Court for the District of
 24 Columbia.

1 ~~of clause~~“(iv) INTEREST ON ANY AMOUNTS IN
2 CONTROVERSY.—Where a provider of serv-
3 ices or supplier is granted judicial review
4 pursuant to this paragraph, the amount in
5 controversy (if any) shall be subject to an-
6 nual interest beginning on the first day of
7 the first month beginning after the 60-day
8 period as determined pursuant to clause
9 (ii) and equal to the rate of interest on ob-
10 ligations issued for purchase by the Fed-
11 eral Supplementary Medical Insurance
12 Trust Fund for the month in which the
13 civil action authorized under this para-
14 graph is commenced, to be awarded by the
15 reviewing court in favor of the prevailing
16 party. No interest awarded pursuant to the
17 preceding sentence shall be deemed income
18 or cost for the purposes of determining re-
19 imbursement due providers of services,
20 physicians, practitioners, and other sup-
21 pliers under this Act. (PUBLISHED)

22 (D) REVIEW ENTITY DEFINED.—For pur-
23 poses of this subsection, the term ‘review entity’
24 means an entity of up to 3 qualified reviewers

1 drawn from existing appeals levels other than
2 the redetermination level.

3 (b) APPLICATION TO PROVIDER AGREEMENT DETER-
4 MINATIONS.—Section 1866(h)(1) (42 U.S.C.
5 1395cc(h)(1)) is amended—

6 (1) by inserting “(A)” after “(h)(1)”; and

7 (2) by adding at the end the following new sub-
8 paragraph:

9 “(B) An institution or agency described in subpara-
10 graph (A) that has filed for a hearing under subparagraph
11 (A) shall have expedited access to judicial review under
12 this subparagraph in the same manner as providers of
13 services, suppliers, and beneficiaries may obtain expedited
14 access to judicial review under the process established
15 under section 1869(b)(2). Nothing in this subparagraph
16 shall be construed to affect the application of any remedy
17 imposed under section 1819 during the pendency of an
18 appeal under this subparagraph.”.

19 (c) GAO STUDY AND REPORT ON ACCESS TO JUDI-
20 CIAL REVIEW.—

21 (1) STUDY.—The Comptroller General of the
22 United States shall conduct a study on the access of
23 Medicare beneficiaries and health care providers to
24 judicial review of actions of the Secretary and the
25 Department of Health and Human Services with re-

spect to items and services under title XVIII of the Social Security Act subsequent to February 29, 2000, the date of the decision of Shalala, Secretary of Health and Human Services, et al. v. Illinois Council on Long Term Care, Inc. (529 U.S. 1 (2000)).

(2) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations as the Comptroller General determines to be appropriate.

(d) CONFORMING AMENDMENT.—Section 1869(b)(1)(F)(ii) (42 U.S.C. 1395ff(b)(1)(F)(ii)) is amended to read as follows:

“(ii) REFERENCE TO EXPEDITED ACCESS TO JUDICIAL REVIEW.—For the provision relating to expedited access to judicial review, see paragraph (2).”.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2004.

1 **SEC. 513. EXPEDITED REVIEW OF CERTAIN PROVIDER**
2 **AGREEMENT DETERMINATIONS.**

3 (a) **TERMINATION AND CERTAIN OTHER IMMEDIATE**
4 **REMEDIES.—**

5 (1) **IN GENERAL.**—The Secretary shall develop
6 and implement a process to expedite proceedings
7 under sections 1866(h) of the Social Security Act
8 (42 U.S.C. 1395cc(h)) in which—

9 (A) the remedy of termination of participa-
10 tion has been imposed;

11 (B) a sanction described in clause (i) or
12 (iii) of section 1819(h)(2)(B) of such Act (42
13 U.S.C. 1395i-3(h)(2)(B)) has been imposed,
14 but only if such sanction has been imposed on
15 an immediate basis; or

16 (C) the Secretary has required a skilled
17 nursing facility to suspend operations of a
18 nurse aide training program.

19 (2) **PRIORITY FOR CASES OF TERMINATION.—**

20 Under the process described in paragraph (1), pri-
21 ority shall be provided in cases of termination de-
22 scribed in subparagraph (A) of such paragraph.

23 (b) **INCREASED FINANCIAL SUPPORT.**—In addition
24 to any amounts otherwise appropriated, to reduce by 50
25 percent the average time for administrative determina-
26 tions on appeals under section 1866(h) of the Social Secu-

1 rity Act (42 U.S.C. 1395cc(h)), there are authorized to
 2 be appropriated (in appropriate part from the Federal
 3 Hospital Insurance Trust Fund and the Federal Supple-
 4 mentary Medical Insurance Trust Fund) to the Secretary
 5 such sums for fiscal year 2004 and each subsequent fiscal
 6 year as may be necessary to increase the number of ad-
 7 ministrative law judges (and their staffs) at the Depart-
 8 mental Appeals Board of the Department of Health and
 9 Human Services and to educate such judges and staff on
 10 long-term care issues.

11 **SEC. 514. REVISIONS TO MEDICARE APPEALS PROCESS.**

12 (a) TIMEFRAMES FOR THE COMPLETION OF THE
 13 RECORD.—Section 1869(b) (42 U.S.C. 1395ff(b)), as
 14 amended by section 512(a)(2), is amended by adding at
 15 the end the following new paragraph:

16 “(3) TIMELY COMPLETION OF THE RECORD.—

17 “(A) DEADLINE.—Subject to subpara-
 18 graph (B), the deadline to complete the record
 19 in a hearing before an administrative law judge
 20 or a review by the Departmental Appeals Board
 21 is 90 days after the date the request for the re-
 22 view or hearing is filed.

23 “(B) EXTENSIONS FOR GOOD CAUSE.—

24 The person filing a request under subparagraph
 25 (A) may request an extension of such deadline

1 for good cause. The administrative law judge,
 2 in the case of a hearing, and the Departmental
 3 Appeals Board, in the case of a review, may ex-
 4 tend such deadline based upon a finding of
 5 good cause to a date specified by the judge or
 6 the Board, as the case may be.

7 “(C) DELAY IN DECISION DEADLINES
 8 UNTIL COMPLETION OF RECORD.—Notwith-
 9 standing any other provision of this section, the
 10 deadlines otherwise established under sub-
 11 section (d) for the making of determinations in
 12 hearings or review under this section are 90
 13 days after the date on which the record is com-
 14 plete.

15 “(D) COMPLETE RECORD DESCRIBED.—
 16 For purposes of this paragraph, a record is
 17 complete when the administrative law judge, in
 18 the case of a hearing, or the Departmental Ap-
 19 peals Board, in the case of a review, has re-
 20 ceived—

21 “(i) written or testimonial evidence, or
 22 both, submitted by the person filing the re-
 23 quest,

24 “(ii) written or oral argument, or
 25 both,

“(iii) the decision of, and the record for, the prior level of appeal, and
 “(iv) such other evidence as such judge or Board, as the case may be, determines is required to make a determination on the request.”.

(b) USE OF PATIENTS’ MEDICAL RECORDS.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)) is amended by inserting “(including the medical records of the individual involved)” after “clinical experience”.

(c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

(1) INITIAL DETERMINATIONS AND REDETERMINATIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)) is amended by adding at the end the following new paragraph:

“(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS AND REDETERMINATIONS.—A written notice of a determination on an initial determination or on a redetermination, insofar as such determination or redetermination results in a denial of a claim for benefits, shall be provided in printed form and written in a manner to be understood by the beneficiary and shall include—

1 “(A) the reasons for the determination, in-
2 cluding, as appropriate—

3 “(i) upon request in the case of an
4 initial determination, the provision of the
5 policy, manual, or regulation that resulted
6 in the denial; and

7 “(ii) in the case of a redetermination,
8 a summary of the clinical or scientific evi-
9 dence used in making the determination
10 (as appropriate);

11 “(B) the procedures for obtaining addi-
12 tional information concerning the determination
13 or redetermination; and

14 “(C) notification of the right to seek a re-
15 determination or otherwise appeal the deter-
16 mination and instructions on how to initiate
17 such a redetermination or appeal under this
18 section.”.

19 (2) RECONSIDERATIONS.—Section
20 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)) is
21 amended to read as follows:

22 “(E) EXPLANATION OF DECISION.—Any
23 decision with respect to a reconsideration of a
24 qualified independent contractor shall be in

writing in a manner to be understood by the
beneficiary and shall include—

“(i) to the extent appropriate, a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision;

“(ii) a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section; and

“(iii) in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)) an explanation of the medical or scientific rationale for the decision.”.

(3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)) is amended—

(A) in the heading, by inserting “; NOTICE” after “SECRETARY”; and

(B) by adding at the end the following new paragraph:

1 “(4) NOTICE.—Notice of the decision of an ad-
 2 ministrative law judge shall be in writing in a man-
 3 ner to be understood by the beneficiary and shall in-
 4 clude—

5 “(A) the specific reasons for the deter-
 6 mination (including, to the extent appropriate,
 7 a summary of the clinical or scientific evidence
 8 used in making the determination);

9 “(B) the procedures for obtaining addi-
 10 tional information concerning the decision; and

11 “(C) notification of the right to appeal the
 12 decision and instructions on how to initiate
 13 such an appeal under this section.”.

14 (4) PREPARATION OF RECORD FOR APPEAL.—
 15 Section 1869(c)(3)(J) (42 U.S.C. 1395ff(c)(3)(J)) is
 16 amended by striking “such information as is re-
 17 quired for an appeal” and inserting “the record for
 18 the appeal”.

19 (d) QUALIFIED INDEPENDENT CONTRACTORS.—

20 (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED
 21 INDEPENDENT CONTRACTORS.—Section 1869(c) (42
 22 U.S.C. 1395ff(c)) is amended—

23 (A) in paragraph (2)—

24 (i) by inserting “(except in the case of
 25 a utilization and quality control peer re-

view organization, as defined in section 1025.1152)” after “means an entity or organization that”; and

(ii) by striking the period at the end and inserting the following: “and meets the following requirements:

“(A) GENERAL REQUIREMENTS.—

“(i) The entity or organization has (directly or through contracts or other arrangements) sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing to carry out duties of a qualified independent contractor under this section on a timely basis.

“(ii) The entity or organization has provided assurances that it will conduct activities consistent with the applicable requirements of this section, including that it will not conduct any activities in a case unless the independence requirements of subparagraph (B) are met with respect to the case.

1 “(iii) The entity or organization meets
2 such other requirements as the Secretary
3 provides by regulation.

4 “(B) INDEPENDENCE REQUIREMENTS.—

5 “(i) IN GENERAL.—Subject to clause
6 (ii), an entity or organization meets the
7 independence requirements of this sub-
8 paragraph with respect to any case if the
9 entity—

10 “(I) is not a related party (as de-
11 fined in subsection (g)(5));

12 “(II) does not have a material fa-
13 milial, financial, or professional rela-
14 tionship with such a party in relation
15 to such case; and

16 “(III) does not otherwise have a
17 conflict of interest with such a party
18 (as determined under regulations).

19 “(ii) EXCEPTION FOR COMPENSA-
20 TION.—Nothing in clause (i) shall be con-
21 strued to prohibit receipt by a qualified
22 independent contractor of compensation
23 from the Secretary for the conduct of ac-
24 tivities under this section if the compensa-
25 tion is provided consistent with clause (iii).

1 “(iii) LIMITATIONS ON ENTITY COM-
 2 PENSATION.—Compensation provided by
 3 the Secretary to a qualified independent
 4 contractor in connection with reviews
 5 under this section shall not be contingent
 6 on any decision rendered by the contractor
 7 or by any reviewing professional.”; and

8 (B) in paragraph (3)(A), by striking “,
 9 and shall have sufficient training and expertise
 10 in medical science and legal matters to make
 11 reconsiderations under this subsection”.

12 (2) ELIGIBILITY REQUIREMENTS FOR REVIEW-
 13 ERS.—Section 1869 (42 U.S.C. 1395ff) is amend-
 14 ed—

15 (A) by amending subsection (c)(3)(D) to
 16 read as follows: ~~“(D) QUALIFICATIONS OF REVIEWERS.—~~

17 “(D) QUALIFICATIONS OF REVIEWERS.—
 18 The requirements of subsection (g) shall be met
 19 (relating to qualifications of reviewing profes-
 20 sionals).”; and ~~“(E) QUALIFICATIONS OF REVIEWERS.—~~

21 (B) by adding at the end the following new
 22 subsection:

23 “(g) QUALIFICATIONS OF REVIEWERS.—

1 “(1) IN GENERAL.—In reviewing determina-
 2 tions under this section, a qualified independent con-
 3 tractor shall assure that—

4 “(A) each individual conducting a review
 5 shall meet the qualifications of paragraph (2);

6 “(B) compensation provided by the con-
 7 tractor to each such reviewer is consistent with
 8 paragraph (3); and

9 “(C) in the case of a review by a panel de-
 10 scribed in subsection (c)(3)(B) composed of
 11 physicians or other health care professionals
 12 (each in this subsection referred to as a ‘review-
 13 ing professional’), each reviewing professional
 14 meets the qualifications described in paragraph
 15 (4).

16 “(2) INDEPENDENCE.—

17 “(A) IN GENERAL.—Subject to subpara-
 18 graph (B), each individual conducting a review
 19 in a case shall—

20 “(i) not be a related party (as defined
 21 in paragraph (5));

22 “(ii) not have a material familial, fi-
 23 nancial, or professional relationship with
 24 such a party in the case under review; and

“(iii) not otherwise have a conflict of interest with such a party (as determined under regulations).

“(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

“(i) prohibit an individual, solely on the basis of affiliation with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

“(I) a nonaffiliated individual is not reasonably available;

“(II) the affiliated individual is not involved in the provision of items or services in the case under review;

“(III) the fact of such an affiliation is disclosed to the Secretary and the beneficiary (or authorized representative) and neither party objects; and

“(IV) the affiliated individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

1 “(ii) prohibit an individual who has
 2 staff privileges at the institution where the
 3 treatment involved takes place from serv-
 4 ing as a reviewer merely on the basis of
 5 such affiliation if the affiliation is disclosed
 6 to the Secretary and the beneficiary (or
 7 authorized representative), and neither
 8 party objects; or

9 “(iii) prohibit receipt of compensation
 10 by a reviewing professional from a con-
 11 tractor if the compensation is provided
 12 consistent with paragraph (3).

13 “(3) LIMITATIONS ON REVIEWER COMPENSA-
 14 TION.—Compensation provided by a qualified inde-
 15 pendent contractor to a reviewer in connection with
 16 a review under this section shall not be contingent
 17 on the decision rendered by the reviewer.

18 “(4) LICENSURE AND EXPERTISE.—Each re-
 19 viewing professional shall be a physician (allopathic
 20 or osteopathic) or health care professional who—

21 “(A) is appropriately credentialed or li-
 22 censed in 1 or more States to deliver health
 23 care services; and

1 “(B) has medical expertise in the field of
2 practice that is appropriate for the items or
3 services at issue. **REPEATED**

4 “(5) RELATED PARTY DEFINED.—For purposes
5 of this section, the term ‘related party’ means, with
6 respect to a case under this title involving an indi-
7 vidual beneficiary, any of the following:

8 “(A) The Secretary, the medicare adminis-
9 trative contractor involved, or any fiduciary, of-
10 ficer, director, or employee of the Department
11 of Health and Human Services, or of such con-
12 tractor.

13 “(B) The individual (or authorized rep-
14 resentative). **REPEATED REFERENCE TO THE BENEFIT**

15 “(C) The health care professional that pro-
16 vides the items or services involved in the case.

17 “(D) The institution at which the items or
18 services (or treatment) involved in the case are
19 provided. **REPEATED REFERENCE**

20 “(E) The manufacturer of any drug or
21 other item that is included in the items or serv-
22 ices involved in the case.

23 “(F) Any other party determined under
24 any regulations to have a substantial interest in
25 the case involved.”. **DEFINITION**

1 (3) NUMBER OF QUALIFIED INDEPENDENT
 2 CONTRACTORS.—Section 1869(c)(4) (42 U.S.C.
 3 1395ff(c)(4)) is amended by striking “12” and in-
 4 serting “4”.

5 (e) IMPLEMENTATION OF CERTAIN BIPA RE-
 6 FORMS.—

7 (1) DELAY IN CERTAIN BIPA REFORMS.—Sec-
 8 tion 521(d) of BIPA (114 Stat. 2763A-543) is
 9 amended to read as follows:

10 “(d) EFFECTIVE DATE.—

11 “(1) IN GENERAL.—Except as specified in
 12 paragraph (2), the amendments made by this section
 13 shall apply with respect to initial determinations
 14 made on or after December 1, 2004.

15 “(2) EXPEDITED PROCEEDINGS AND RECONSID-
 16 ERATION REQUIREMENTS.—For the following provi-
 17 sions, the amendments made by subsection (a) shall
 18 apply with respect to initial determinations made on
 19 or after October 1, 2003:

20 “(A) Subsection (b)(1)(F)(i) of section
 21 1869 of the Social Security Act.

22 “(B) Subsection (c)(3)(C)(iii) of such sec-
 23 tion.

24 “(C) Subsection (c)(3)(C)(iv) of such sec-
 25 tion to the extent that it applies to expedited

reconsiderations under subsection (c)(3)(C)(iii) of such section.

“(3) TRANSITIONAL USE OF PEER REVIEW ORGANIZATIONS TO CONDUCT EXPEDITED RECONSIDERATIONS UNTIL QICS ARE OPERATIONAL.—Expedited reconsiderations of initial determinations under section 1869(c)(3)(C)(iii) of the Social Security Act shall be made by peer review organizations until qualified independent contractors are available for such expedited reconsiderations.”.

(2) CONFORMING AMENDMENTS.—Section 521(c) of BIPA (114 Stat. 2763A–543) and section 1869(c)(3)(C)(iii)(III) of the Social Security Act (42 U.S.C. 1395ff(c)(3)(C)(iii)(III)), as added by section 521 of BIPA, are repealed.

(f) EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA, 114 Stat. 2763A–534.

(g) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by subsection (d)(2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C.

1 1395h) and a carrier under section 1842 of such Act (42
2 U.S.C. 1395u).

3 **SEC. 515. HEARING RIGHTS RELATED TO DECISIONS BY**
4 **THE SECRETARY TO DENY OR NOT RENEW A**
5 **MEDICARE ENROLLMENT AGREEMENT; CON-**
6 **SULTATION BEFORE CHANGING PROVIDER**
7 **ENROLLMENT FORMS.**

8 (a) HEARING RIGHTS.—

9 (1) IN GENERAL.—Section 1866 (42 U.S.C.
10 1395cc) is amended by adding at the end the fol-
11 lowing new subsection:

12 “(j) HEARING RIGHTS IN CASES OF DENIAL OR
13 NONRENEWAL.—The Secretary shall establish by regula-
14 tion procedures under which—

15 “(1) there are deadlines for actions on applica-
16 tions for enrollment (and, if applicable, renewal of
17 enrollment); and

18 “(2) providers of services, physicians, practi-
19 tioners, and suppliers whose application to enroll
20 (or, if applicable, to renew enrollment) are denied
21 are provided a mechanism to appeal such denial and
22 a deadline for consideration of such appeals.”.

23 (2) EFFECTIVE DATE.—The Secretary shall
24 provide for the establishment of the procedures

under the amendment made by paragraph (1) within
18 months after the date of enactment of this Act.

(b) CONSULTATION BEFORE CHANGING PROVIDER
ENROLLMENT FORMS.—Section 1871 (42 U.S.C.
1395hh), as amended by sections 502 and 503, is amend-
ed by adding at the end the following new subsection:

“(f) The Secretary shall consult with providers of
services, physicians, practitioners, and suppliers before
making changes in the provider enrollment forms required
of such providers, physicians, practitioners, and suppliers
to be eligible to submit claims for which payment may be
made under this title.”.

**SEC. 516. APPEALS BY PROVIDERS WHEN THERE IS NO
OTHER PARTY AVAILABLE.**

(a) IN GENERAL.—Section 1870 (42 U.S.C. 1395gg)
is amended by adding at the end the following new sub-
section:

“(h) Notwithstanding subsection (f) or any other pro-
vision of law, the Secretary shall permit a provider of serv-
ices, physician, practitioner, or other supplier to appeal
any determination of the Secretary under this title relating
to services rendered under this title to an individual who
subsequently dies if there is no other party available to
appeal such determination.”.

1 (b) EFFECTIVE DATE.—The amendment made by
 2 subsection (a) shall take effect on the date of enactment
 3 of this Act and shall apply to items and services furnished
 4 on or after such date.

5 **SEC. 517. PROVIDER ACCESS TO REVIEW OF LOCAL COV-**
 6 **ERAGE DETERMINATIONS.**

7 (a) PROVIDER ACCESS TO REVIEW OF LOCAL COV-
 8 ERAGE DETERMINATIONS.—Section 1869(f)(5) (42
 9 U.S.C. 1395ff(f)(5)) is amended to read as follows:

10 “(5) AGGRIEVED PARTY DEFINED.—In this sec-
 11 tion, the term ‘aggrieved party’ means—

12 “(A) with respect to a national coverage
 13 determination, an individual entitled to benefits
 14 under part A, or enrolled under part B, or both,
 15 who is in need of the items or services that are
 16 the subject of the coverage determination; and

17 “(B) with respect to a local coverage deter-
 18 mination—

19 “(i) an individual who is entitled to
 20 benefits under part A, or enrolled under
 21 part B, or both, who is adversely affected
 22 by such a determination; or

23 “(ii) a provider of services, physician,
 24 practitioner, or supplier that is adversely
 25 affected by such a determination.”.

1 (b) CLARIFICATION OF LOCAL COVERAGE DETER-
 2 MINATION DEFINITION.—Section 1869(f)(2)(B) (42
 3 U.S.C. 1395ff(f)(2)(B)) is amended by inserting “, includ-
 4 ing, where appropriate, the specific requirements and clin-
 5 ical indications relating to the medical necessity of an item
 6 or service” before the period at the end.

7 (c) REQUEST FOR LOCAL COVERAGE DETERMINA-
 8 TIONS BY PROVIDERS.—Section 1869 (42 U.S.C. 1395ff),
 9 as amended by section 514(d)(2)(B), is amended by add-
 10 ing at the end the following new subsection:

11 “(h) REQUEST FOR LOCAL COVERAGE DETERMINA-
 12 TIONS BY PROVIDERS.—

13 “(1) ESTABLISHMENT OF PROCESS.—The Sec-
 14 retary shall establish a process under which a pro-
 15 vider of services, physician, practitioner, or supplier
 16 who certifies that they meet the requirements estab-
 17 lished in paragraph (3) may request a local coverage
 18 determination in accordance with the succeeding
 19 provisions of this subsection.

20 “(2) PROVIDER LOCAL COVERAGE DETERMINA-
 21 TION REQUEST DEFINED.—In this subsection, the
 22 term ‘provider local coverage determination request’
 23 means a request, filed with the Secretary, at such
 24 time and in such form and manner as the Secretary
 25 may specify, that the Secretary, pursuant to para-

graph (4)(A), require a fiscal intermediary, carrier, or program safeguard contractor to make or revise a local coverage determination under this section with respect to an item or service.

“(3) REQUEST REQUIREMENTS.—Under the process established under paragraph (1), by not later than 30 days after the date on which a provider local coverage determination request is filed under paragraph (1), the Secretary shall determine whether such request establishes that—

“(A) there have been at least 5 reversals of redeterminations made by a fiscal intermediary or carrier after a hearing before an administrative law judge on claims submitted by the provider in at least 2 different cases before an administrative law judge;

“(B) each reversal described in subparagraph (A) involves substantially similar material facts;

“(C) each reversal described in subparagraph (A) involves the same medical necessity issue; and

“(D) at least 50 percent of the total number of claims submitted by such provider within the past year involving the substantially similar

1 material facts described in subparagraph (B)
2 and the same medical necessity issue described
3 in subparagraph (C) have been denied and have
4 been reversed by an administrative law judge.

5 “(4) APPROVAL OR REJECTION OF REQUEST.—

6 “(A) APPROVAL OF REQUEST.—If the Sec-
7 retary determines that subparagraphs (A)
8 through (D) of paragraph (3) have been satis-
9 fied, the Secretary shall require the fiscal inter-
10 mediary, carrier, or program safeguard con-
11 tractor identified in the provider local coverage
12 determination request, to make or revise a local
13 coverage determination with respect to the item
14 or service that is the subject of the request not
15 later than the date that is 210 days after the
16 date on which the Secretary makes the deter-
17 mination. Such fiscal intermediary, carrier, or
18 program safeguard contractor shall retain the
19 discretion to determine whether or not, and/or
20 the circumstances under which, to cover the
21 item or service for which a local coverage deter-
22 mination is requested. Nothing in this sub-
23 section shall be construed to require a fiscal
24 intermediary, carrier or program safeguard con-
25 tractor to develop a local coverage determina-

tion that is inconsistent with any national coverage determination, or any coverage provision in this title or in regulation, manual, or interpretive guidance of the Secretary.

“(B) REJECTION OF REQUEST.—If the Secretary determines that subparagraphs (A) through (D) of paragraph (3) have not been satisfied, the Secretary shall reject the provider local coverage determination request and shall notify the provider of services, physician, practitioner, or supplier that filed the request of the reason for such rejection and no further proceedings in relation to such request shall be conducted.”.

(d) STUDY AND REPORT ON THE USE OF CONTRACTORS TO MONITOR MEDICARE APPEALS.—

(1) STUDY.—The Secretary shall conduct a study on the feasibility and advisability of requiring fiscal intermediaries and carriers to monitor and track—

(A) the subject matter and status of claims denied by the fiscal intermediary or carrier (as applicable) that are appealed under section 1869 of the Social Security Act (42 U.S.C. 1395ff), as added by section 522 of BIPA (114

Stat. 2763A-543) and amended by this Act;
and

(B) any final determination made with respect to such claims.

(2) REPORT.—Not later than the date that is 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations for legislation and administrative action as the Commission determines appropriate.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out the amendments made by subsections (a), (b), and (c).

(f) EFFECTIVE DATES.—

(1) PROVIDER ACCESS TO REVIEW OF LOCAL COVERAGE DETERMINATIONS.—The amendments made by subsections (a) and (b) shall apply to—

(A) any review of any local coverage determination filed on or after October 1, 2003;

(B) any request to make such a determination made on or after such date; or

(C) any local coverage determination made on or after such date.

1 (2) PROVIDER LOCAL COVERAGE DETERMINA-
 2 TION REQUESTS.—The amendment made by sub-
 3 section (c) shall apply with respect to provider local
 4 coverage determination requests (as defined in sec-
 5 tion 1869(h)(2) of the Social Security Act, as added
 6 by subsection (c)) filed on or after the date of enact-
 7 ment of this Act.

8 **SEC. 518. REVISIONS TO APPEALS TIMEFRAMES.**

9 Section 1869 (42 U.S.C. 1395ff) is amended—

10 (1) in subsection (a)(3)(C)(ii), by striking “30-
 11 day period” each place it appears and inserting “60-
 12 day period”;

13 (2) in subsection (c)(3)(C)(i), by striking “30-
 14 day period” and inserting “60-day period”;

15 (3) in subsection (d)(1)(A), by striking “90-day
 16 period” and inserting “120-day period”; and

17 (4) in subsection (d)(2)(A), by striking “90-day
 18 period” and inserting “120-day period”.

19 **SEC. 519. ELIMINATION OF REQUIREMENT TO USE SOCIAL**
 20 **SECURITY ADMINISTRATION ADMINISTRA-**
 21 **TIVE LAW JUDGES.**

22 The first sentence of section 1869(f)(2)(A)(i) (42
 23 U.S.C. 1395ff(f)(2)(A)(i)) is amended by striking “of the
 24 Social Security Administration”.

1 **SEC. 520. ELIMINATION OF REQUIREMENT FOR DE NOVO**
 2 **REVIEW BY THE DEPARTMENTAL APPEALS**
 3 **BOARD.**

4 Section 1869(d)(2) (42 U.S.C. 1395ff(d)(2)) is
 5 amended to read as follows:

6 “(2) DEPARTMENTAL APPEALS BOARD RE-
 7 VIEW.—The Departmental Appeals Board of the De-
 8 partment of Health and Human Services shall con-
 9 duct and conclude a review of the decision on a
 10 hearing described in paragraph (1) and make a deci-
 11 sion or remand the case to the administrative law
 12 judge for reconsideration by not later than the end
 13 of the 90-day period beginning on the date a request
 14 for review has been timely filed.”.

15 **Subtitle C—Contracting Reform**

16 **SEC. 521. INCREASED FLEXIBILITY IN MEDICARE ADMINIS-**
 17 **TRATION.**

18 (a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE
 19 ADMINISTRATION.—

20 (1) IN GENERAL.—Title XVIII is amended by
 21 inserting after section 1874 the following new sec-
 22 tion:

23 “CONTRACTS WITH MEDICARE ADMINISTRATIVE
 24 CONTRACTORS

25 “SEC. 1874A. (a) AUTHORITY.—

1 “(1) AUTHORITY TO ENTER INTO CON-
 2 TRACTS.—The Secretary may enter into contracts
 3 with any eligible entity to serve as a medicare ad-
 4 ministrative contractor with respect to the perform-
 5 ance of any or all of the functions described in para-
 6 graph (4) or parts of those functions (or, to the ex-
 7 tent provided in a contract, to secure performance
 8 thereof by other entities).

9 “(2) ELIGIBILITY OF ENTITIES.—An entity is
 10 eligible to enter into a contract with respect to the
 11 performance of a particular function described in
 12 paragraph (4) only if—

13 “(A) the entity has demonstrated capa-
 14 bility to carry out such function;

15 “(B) the entity complies with such conflict
 16 of interest standards as are generally applicable
 17 to Federal acquisition and procurement;

18 “(C) the entity has sufficient assets to fi-
 19 nancially support the performance of such func-
 20 tion; and

21 “(D) the entity meets such other require-
 22 ments as the Secretary may impose.

23 “(3) MEDICARE ADMINISTRATIVE CONTRACTOR
 24 DEFINED.—For purposes of this title and title XI—

1 “(A) IN GENERAL.—The term ‘medicare
2 administrative contractor’ means an agency, or-
3 ganization, or other person with a contract
4 under this section.

5 “(B) APPROPRIATE MEDICARE ADMINIS-
6 TRATIVE CONTRACTOR.—With respect to the
7 performance of a particular function in relation
8 to an individual entitled to benefits under part
9 A or enrolled under part B, or both, a specific
10 provider of services, physician, practitioner, fa-
11 cility, or supplier (or class of such providers of
12 services, physicians, practitioners, facilities, or
13 suppliers), the ‘appropriate’ medicare adminis-
14 trative contractor is the medicare administra-
15 tive contractor that has a contract under this
16 section with respect to the performance of that
17 function in relation to that individual, provider
18 of services, physician, practitioner, facility, or
19 supplier or class of provider of services, physi-
20 cian, practitioner, facility, or supplier.

21 “(4) FUNCTIONS DESCRIBED.—The functions
22 referred to in paragraphs (1) and (2) are payment
23 functions (including the function of developing local
24 coverage determinations, as defined in section

1 1869(f)(2)(B)), provider services functions, and ben-
 2 eficiary services functions as follows:

3 “(A) DETERMINATION OF PAYMENT
 4 AMOUNTS.—Determining (subject to the provi-
 5 sions of section 1878 and to such review by the
 6 Secretary as may be provided for by the con-
 7 tracts) the amount of the payments required
 8 pursuant to this title to be made to providers
 9 of services, physicians, practitioners, facilities,
 10 suppliers, and individuals.

11 “(B) MAKING PAYMENTS.—Making pay-
 12 ments described in subparagraph (A) (including
 13 receipt, disbursement, and accounting for funds
 14 in making such payments).

15 “(C) BENEFICIARY EDUCATION AND AS-
 16 SISTANCE.—Serving as a center for, and com-
 17 municating to individuals entitled to benefits
 18 under part A or enrolled under part B, or both,
 19 with respect to education and outreach for
 20 those individuals, and assistance with specific
 21 issues, concerns, or problems of those individ-
 22 uals.

23 “(D) PROVIDER CONSULTATIVE SERV-
 24 ICES.—Providing consultative services to insti-
 25 tutions, agencies, and other persons to enable

1 them to establish and maintain fiscal records
2 necessary for purposes of this title and other-
3 wise to qualify as providers of services, physi-
4 cians, practitioners, facilities, or suppliers.

5 “(E) COMMUNICATION WITH PRO-
6 VIDERS.—Serving as a center for, and commu-
7 nicating to providers of services, physicians,
8 practitioners, facilities, and suppliers, any infor-
9 mation or instructions furnished to the medi-
10 care administrative contractor by the Secretary,
11 and serving as a channel of communication
12 from such providers, physicians, practitioners,
13 facilities, and suppliers to the Secretary.

14 “(F) PROVIDER EDUCATION AND TECH-
15 NICAL ASSISTANCE.—Performing the functions
16 described in subsections (e) and (f), relating to
17 education, training, and technical assistance to
18 providers of services, physicians, practitioners,
19 facilities, and suppliers.

20 “(G) ADDITIONAL FUNCTIONS.—Per-
21 forming such other functions, including (subject
22 to paragraph (5)) functions under the Medicare
23 Integrity Program under section 1893, as are
24 necessary to carry out the purposes of this title.

25 “(5) RELATIONSHIP TO MIP CONTRACTS.—

1 “(A) NONDUPLICATION OF ACTIVITIES.—

2 In entering into contracts under this section,
 3 the Secretary shall assure that activities of
 4 medicare administrative contractors do not du-
 5 plicate activities carried out under contracts en-
 6 tered into under the Medicare Integrity Pro-
 7 gram under section 1893. The previous sen-
 8 tence shall not apply with respect to the activity
 9 described in section 1893(b)(5) (relating to
 10 prior authorization of certain items of durable
 11 medical equipment under section 1834(a)(15)).

12 “(B) CONSTRUCTION.—An entity shall not

13 be treated as a medicare administrative con-
 14 tractor merely by reason of having entered into
 15 a contract with the Secretary under section
 16 1893.

17 “(6) APPLICATION OF FEDERAL ACQUISITION

18 REGULATION.—Except to the extent inconsistent
 19 with a specific requirement of this title, the Federal
 20 Acquisition Regulation applies to contracts under
 21 this title.

22 “(b) CONTRACTING REQUIREMENTS.—

23 “(1) USE OF COMPETITIVE PROCEDURES.—

24 “(A) IN GENERAL.—Except as provided in
 25 laws with general applicability to Federal acqui-

sition and procurement, the Federal Acquisition Regulation, or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section.

“(B) RENEWAL OF CONTRACTS.—The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every 6 years.

“(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors without regard to any provision of law requiring competition. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide notice (whether in the Fed-

1 eral Register or otherwise) of any such transfer
 2 (including a description of the functions so
 3 transferred and contact information for the
 4 contractors involved) to providers of services,
 5 physicians, practitioners, facilities, and sup-
 6 pliers affected by the transfer.

7 “(D) INCENTIVES FOR QUALITY.—The
 8 Secretary may provide incentives for medicare
 9 administrative contractors to provide quality
 10 service and to promote efficiency.

11 “(2) COMPLIANCE WITH REQUIREMENTS.—No
 12 contract under this section shall be entered into with
 13 any medicare administrative contractor unless the
 14 Secretary finds that such medicare administrative
 15 contractor will perform its obligations under the con-
 16 tract efficiently and effectively and will meet such
 17 requirements as to financial responsibility, legal au-
 18 thority, and other matters as the Secretary finds
 19 pertinent.

20 “(3) PERFORMANCE REQUIREMENTS.—

21 “(A) DEVELOPMENT OF SPECIFIC PER-
 22 FORMANCE REQUIREMENTS.—The Secretary
 23 shall develop contract performance require-
 24 ments to carry out the specific requirements ap-
 25 plicable under this title to a function described

in subsection (a)(4) and shall develop standards for measuring the extent to which a contractor has met such requirements. In developing such performance requirements and standards for measurement, the Secretary shall consult with providers of services, organizations representative of beneficiaries under this title, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements. The Secretary shall make such performance requirements and measurement standards available to the public.

“(B) CONSIDERATIONS.—The Secretary shall include, as 1 of the standards, provider and beneficiary satisfaction levels.

“(C) INCLUSION IN CONTRACTS.—All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

“(i) shall reflect the performance requirements published under subparagraph (A), but may include additional performance requirements;

1 “(ii) shall be used for evaluating con-
2 tractor performance under the contract;
3 and

4 “(iii) shall be consistent with the writ-
5 ten statement of work provided under the
6 contract.

7 “(4) INFORMATION REQUIREMENTS.—The Sec-
8 retary shall not enter into a contract with a medi-
9 care administrative contractor under this section un-
10 less the contractor agrees—

11 “(A) to furnish to the Secretary such time-
12 ly information and reports as the Secretary may
13 find necessary in performing his functions
14 under this title; and

15 “(B) to maintain such records and afford
16 such access thereto as the Secretary finds nec-
17 essary to assure the correctness and verification
18 of the information and reports under subpara-
19 graph (A) and otherwise to carry out the pur-
20 poses of this title.

21 “(5) SURETY BOND.—A contract with a medi-
22 care administrative contractor under this section
23 may require the medicare administrative contractor,
24 and any of its officers or employees certifying pay-
25 ments or disbursing funds pursuant to the contract,

or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

“(6) RETAINING DIVERSITY OF LOCAL COVERAGE DETERMINATIONS.—A contract with a medicare administrative contractor under this section to perform the function of developing local coverage determinations (as defined in section 1869(f)(2)(B)) shall provide that the contractor shall—

“(A) designate at least 1 different individual to serve as medical director for each State for which such contract performs such function;

“(B) utilize such medical director in the performance of such function; and

“(C) appoint a contractor advisory committee with respect to each such State to provide a formal mechanism for physicians in the State to be informed of, and participate in, the development of a local coverage determination in an advisory capacity.

“(c) TERMS AND CONDITIONS.—

“(1) IN GENERAL.—Subject to subsection (a)(6), a contract with any medicare administrative

1 contractor under this section may contain such
2 terms and conditions as the Secretary finds nec-
3 essary or appropriate and may provide for advances
4 of funds to the medicare administrative contractor
5 for the making of payments by it under subsection
6 (a)(4)(B).

7 “(2) PROHIBITION ON MANDATES FOR CERTAIN
8 DATA COLLECTION.—The Secretary may not require,
9 as a condition of entering into, or renewing, a con-
10 tract under this section, that the medicare adminis-
11 trative contractor match data obtained other than in
12 its activities under this title with data used in the
13 administration of this title for purposes of identi-
14 fying situations in which the provisions of section
15 1862(b) may apply.

16 “(d) LIMITATION ON LIABILITY OF MEDICARE AD-
17 MINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

18 “(1) CERTIFYING OFFICER.—No individual des-
19 ignated pursuant to a contract under this section as
20 a certifying officer shall, in the absence of the reck-
21 less disregard of the individual’s obligations or the
22 intent by that individual to defraud the United
23 States, be liable with respect to any payments cer-
24 tified by the individual under this section.

1 “(2) DISBURSING OFFICER.—No disbursing of-
2 ficer shall, in the absence of the reckless disregard
3 of the officer’s obligations or the intent by that offi-
4 cer to defraud the United States, be liable with re-
5 spect to any payment by such officer under this sec-
6 tion if it was based upon an authorization (which
7 meets the applicable requirements for such internal
8 controls established by the Comptroller General) of
9 a certifying officer designated as provided in para-
10 graph (1) of this subsection.

11 “(3) LIABILITY OF MEDICARE ADMINISTRATIVE
12 CONTRACTOR.—No medicare administrative con-
13 tractor shall be liable to the United States for a pay-
14 ment by a certifying or disbursing officer unless, in
15 connection with such a payment, the medicare ad-
16 ministrative contractor acted with reckless disregard
17 of its obligations under its medicare administrative
18 contract or with intent to defraud the United States.

19 “(4) RELATIONSHIP TO FALSE CLAIMS ACT.—
20 Nothing in this subsection shall be construed to limit
21 liability for conduct that would constitute a violation
22 of sections 3729 through 3731 of title 31, United
23 States Code (commonly known as the “False Claims
24 Act”).

25 “(5) INDEMNIFICATION BY SECRETARY.—

1 “(A) IN GENERAL.—Notwithstanding any
2 other provision of law and subject to the suc-
3 ceeding provisions of this paragraph, in the case
4 of a medicare administrative contractor (or a
5 person who is a director, officer, or employee of
6 such a contractor or who is engaged by the con-
7 tractor to participate directly in the claims ad-
8 ministration process) who is made a party to
9 any judicial or administrative proceeding aris-
10 ing from, or relating directly to, the claims ad-
11 ministration process under this title, the Sec-
12 retary may, to the extent specified in the con-
13 tract with the contractor, indemnify the con-
14 tractor (and such persons).

15 “(B) CONDITIONS.—The Secretary may
16 not provide indemnification under subparagraph
17 (A) insofar as the liability for such costs arises
18 directly from conduct that is determined by the
19 Secretary to be criminal in nature, fraudulent,
20 or grossly negligent.

21 “(C) SCOPE OF INDEMNIFICATION.—In-
22 demnification by the Secretary under subpara-
23 graph (A) may include payment of judgments,
24 settlements (subject to subparagraph (D)),

awards, and costs (including reasonable legal expenses).

“(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate a settlement. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement are conditioned upon the Secretary’s prior written approval of the final settlement.

“(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

“(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

~~provide~~“(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.”.

(2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS.—In developing contract

1 performance requirements under section 1874A(b)
 2 of the Social Security Act (as added by paragraph
 3 (1)) the Secretary shall consider inclusion of the per-
 4 formance standards described in sections 1816(f)(2)
 5 of such Act (relating to timely processing of recon-
 6 siderations and applications for exemptions) and sec-
 7 tion 1842(b)(2)(B) of such Act (relating to timely
 8 review of determinations and fair hearing requests),
 9 as such sections were in effect before the date of en-
 10 actment of this Act.

11 (b) CONFORMING AMENDMENTS TO SECTION 1816
 12 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816
 13 (42 U.S.C. 1395h) is amended as follows:

14 (1) The heading is amended to read as follows:
 15 “PROVISIONS RELATING TO THE ADMINISTRATION OF
 16 PART A”.

17 (2) Subsection (a) is amended to read as fol-
 18 lows:

19 “(a) The administration of this part shall be con-
 20 ducted through contracts with medicare administrative
 21 contractors under section 1874A.”.

22 (3) Subsection (b) is repealed.

23 (4) Subsection (c) is amended—

24 (A) by striking paragraph (1); and

25 (B) in each of paragraphs (2)(A) and

26 (3)(A), by striking “agreement under this sec-

tion” and inserting “contract under section 1874A that provides for making payments under this part”.

(5) Subsections (d) through (i) are repealed.

(6) Subsections (j) and (k) are each amended—

(A) by striking “An agreement with an agency or organization under this section” and inserting “A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part”; and

(B) by striking “such agency or organization” and inserting “such medicare administrative contractor” each place it appears.

(7) Subsection (l) is repealed.

(c) CONFORMING AMENDMENTS TO SECTION 1842 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows:

“PROVISIONS RELATING TO THE ADMINISTRATION OF
PART B”.

(2) Subsection (a) is amended to read as follows:

“(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.”.

(3) Subsection (b) is amended—

1 (A) by striking paragraph (1);

2 (B) in paragraph (2)—

3 (i) by striking subparagraphs (A) and
4 (B);

5 (ii) in subparagraph (C), by striking
6 “carriers” and inserting “medicare admin-
7 istrative contractors”; and

8 (iii) by striking subparagraphs (D)
9 and (E);

10 (C) in paragraph (3)—

11 (i) in the matter before subparagraph
12 (A), by striking “Each such contract shall
13 provide that the carrier” and inserting
14 “The Secretary”;

15 (ii) by striking “will” the first place it
16 appears in each of subparagraphs (A), (B),
17 (F), (G), (H), and (L) and inserting
18 “shall”;

19 (iii) in subparagraph (B), in the mat-
20 ter before clause (i), by striking “to the
21 policyholders and subscribers of the car-
22 rier” and inserting “to the policyholders
23 and subscribers of the medicare adminis-
24 trative contractor”;

1 (iv) by striking subparagraphs (C),
 2 (D), and (E);

3 (v) in subparagraph (H)—

4 (I) by striking “if it makes deter-
 5 minations or payments with respect to
 6 physicians’ services,”; and

7 (II) by striking “carrier” and in-
 8 serting “medicare administrative con-
 9 tractor”;

10 (iv) by striking subparagraph (I);

11 (vii) in subparagraph (L), by striking
 12 the semicolon and inserting a period;

13 (viii) in the first sentence, after sub-
 14 paragraph (L), by striking “and shall con-
 15 tain” and all that follows through the pe-
 16 riod; and

17 (ix) in the seventh sentence, by insert-
 18 ing “medicare administrative contractor,”
 19 after “carrier,”;

20 (D) by striking paragraph (5);

21 (E) in paragraph (6)(D)(iv), by striking
 22 “carrier” and inserting “medicare administra-
 23 tive contractor”; and

1 (F) in paragraph (7), by striking “the car-
2 rier” and inserting “the Secretary” each place
3 it appears.

4 (4) Subsection (c) is amended—

5 (A) by striking paragraph (1);

6 (B) in paragraph (2), by striking “contract
7 under this section which provides for the dis-
8 bursement of funds, as described in subsection
9 (a)(1)(B),” and inserting “contract under sec-
10 tion 1874A that provides for making payments
11 under this part”;

12 (C) in paragraph (3)(A), by striking “sub-
13 section (a)(1)(B)” and inserting “section
14 1874A(a)(3)(B)”;

15 (D) in paragraph (4), by striking “carrier”
16 and inserting “medicare administrative con-
17 tractor”;

18 (E) in paragraph (5), by striking “contract
19 under this section which provides for the dis-
20 bursement of funds, as described in subsection
21 (a)(1)(B), shall require the carrier” and “car-
22 rier responses” and inserting “contract under
23 section 1874A that provides for making pay-
24 ments under this part shall require the medi-

care administrative contractor” and “contractor responses”, respectively; and

(F) by striking paragraph (6).

(5) Subsections (d), (e), and (f) are repealed.

(6) Subsection (g) is amended by striking “carrier or carriers” and inserting “medicare administrative contractor or contractors”.

(7) Subsection (h) is amended—

(A) in paragraph (2)—

(i) by striking “Each carrier having an agreement with the Secretary under subsection (a)” and inserting “The Secretary”; and

(ii) by striking “Each such carrier” and inserting “The Secretary”;

(B) in paragraph (3)(A)—

(i) by striking “a carrier having an agreement with the Secretary under subsection (a)” and inserting “medicare administrative contractor having a contract under section 1874A that provides for making payments under this part”; and

(ii) by striking “such carrier” and inserting “such contractor”;

(C) in paragraph (3)(B)—

1 (i) by striking “a carrier” and insert-
 2 ing “a medicare administrative contractor”
 3 each place it appears; and

4 (ii) by striking “the carrier” and in-
 5 serting “the contractor” each place it ap-
 6 pears; and

7 (D) in paragraphs (5)(A) and (5)(B)(iii),
 8 by striking “carriers” and inserting “medicare
 9 administrative contractors” each place it ap-
 10 pears.

11 (8) Subsection (l) is amended—

12 (A) in paragraph (1)(A)(iii), by striking
 13 “carrier” and inserting “medicare administra-
 14 tive contractor”; and

15 (B) in paragraph (2), by striking “carrier”
 16 and inserting “medicare administrative con-
 17 tractor”.

18 (9) Subsection (p)(3)(A) is amended by striking
 19 “carrier” and inserting “medicare administrative
 20 contractor”.

21 (10) Subsection (q)(1)(A) is amended by strik-
 22 ing “carrier”.

23 (d) EFFECTIVE DATE; TRANSITION RULE.—

24 (1) EFFECTIVE DATE.—

1 (A) IN GENERAL.—Except as otherwise
2 provided in this subsection, the amendments
3 made by this section shall take effect on Octo-
4 ber 1, 2005, and the Secretary is authorized to
5 take such steps before such date as may be nec-
6 essary to implement such amendments on a
7 timely basis.

8 (B) CONSTRUCTION FOR CURRENT CON-
9 TRACTS.—Such amendments shall not apply to
10 contracts in effect before the date specified
11 under subparagraph (A) that continue to retain
12 the terms and conditions in effect on such date
13 (except as otherwise provided under this title,
14 other than under this section) until such date
15 as the contract is let out for competitive bid-
16 ding under such amendments.

17 (C) DEADLINE FOR COMPETITIVE BID-
18 DING.—The Secretary shall provide for the let-
19 ting by competitive bidding of all contracts for
20 functions of medicare administrative contrac-
21 tors for annual contract periods that begin on
22 or after October 1, 2011.

23 (2) GENERAL TRANSITION RULES.—

24 (A) AUTHORITY TO CONTINUE TO ENTER
25 INTO NEW AGREEMENTS AND CONTRACTS AND

1 WAIVER OF PROVIDER NOMINATION PROVISIONS
2 DURING TRANSITION.—Prior to the date speci-
3 fied in paragraph (1)(A), the Secretary may,
4 consistent with subparagraph (B), continue to
5 enter into agreements under section 1816 and
6 contracts under section 1842 of the Social Se-
7 curity Act (42 U.S.C. 1395h, 1395u). The Sec-
8 retary may enter into new agreements under
9 section 1816 during the time period without re-
10 gard to any of the provider nomination provi-
11 sions of such section.

12 (B) APPROPRIATE TRANSITION.—The Sec-
13 retary shall take such steps as are necessary to
14 provide for an appropriate transition from
15 agreements under section 1816 and contracts
16 under section 1842 of the Social Security Act
17 (42 U.S.C. 1395h, 1395u) to contracts under
18 section 1874A, as added by subsection (a)(1).

19 (3) AUTHORIZING CONTINUATION OF MIP AC-
20 TIVITIES UNDER CURRENT CONTRACTS AND AGREE-
21 MENTS AND UNDER TRANSITION CONTRACTS.—The
22 provisions contained in the exception in section
23 1893(d)(2) of the Social Security Act (42 U.S.C.
24 1395ddd(d)(2)) shall continue to apply notwith-
25 standing the amendments made by this section, and

any reference in such provisions to an agreement or contract shall be deemed to include agreements and contracts entered into pursuant to paragraph (2)(A).

(e) REFERENCES.—On and after the effective date provided under subsection (d)(1), any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to an appropriate medicare administrative contractor (as provided under section 1874A of the Social Security Act).

(f) SECRETARIAL SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of enactment of this Act, the Secretary shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this section.

(g) REPORTS ON IMPLEMENTATION.—

(1) PROPOSAL FOR IMPLEMENTATION.—At least 1 year before the date specified in subsection (d)(1)(A), the Secretary shall submit a report to Congress and the Comptroller General of the United States that describes a plan for an appropriate transition. The Comptroller General shall conduct an evaluation of such plan and shall submit to Con-

1 gress, not later than 6 months after the date the re-
 2 port is received, a report on such evaluation and
 3 shall include in such report such recommendations
 4 as the Comptroller General deems appropriate.

5 (2) STATUS OF IMPLEMENTATION.—The Sec-
 6 retary shall submit a report to Congress not later
 7 than October 1, 2008, that describes the status of
 8 implementation of such amendments and that in-
 9 cludes a description of the following:

10 (A) The number of contracts that have
 11 been competitively bid as of such date.

12 (B) The distribution of functions among
 13 contracts and contractors.

14 (C) A timeline for complete transition to
 15 full competition.

16 (D) A detailed description of how the Sec-
 17 retary has modified oversight and management
 18 of medicare contractors to adapt to full com-
 19 petition.

20 **Subtitle D—Education and** 21 **Outreach Improvements**

22 **SEC. 531. PROVIDER EDUCATION AND TECHNICAL ASSIST-** 23 **ANCE.**

24 (a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—The Social Security Act is amended by inserting after section 1888 the following new section:

“PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

“SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (e), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services, physicians, practitioners, and suppliers.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of enactment of this Act.

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 521(a)(1), is amended by adding at the end the following new subsection:

“(e) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—

“(1) METHODOLOGY TO MEASURE CONTRACTOR ERROR RATES.—In order to give medicare contractors (as defined in paragraph (3)) an incentive to implement effective education and outreach programs for providers of services, physicians, practi-

1 tioners, and suppliers, the Secretary shall develop
 2 and implement by October 1, 2004, a methodology
 3 to measure the specific claims payment error rates
 4 of such contractors in the processing or reviewing of
 5 medicare claims.

6 “(2) GAO REVIEW OF METHODOLOGY.—The
 7 Comptroller General of the United States shall re-
 8 view, and make recommendations to the Secretary,
 9 regarding the adequacy of such methodology.

10 “(3) MEDICARE CONTRACTOR DEFINED.—For
 11 purposes of this subsection, the term ‘medicare con-
 12 tractor’ includes a medicare administrative con-
 13 tractor, a fiscal intermediary with a contract under
 14 section 1816, and a carrier with a contract under
 15 section 1842.”.

16 (2) REPORT.—The Secretary shall submit to
 17 Congress a report that describes how the Secretary
 18 intends to use the methodology developed under sec-
 19 tion 1874A(e)(1) of the Social Security Act, as
 20 added by paragraph (1), in assessing medicare con-
 21 tractor performance in implementing effective edu-
 22 cation and outreach programs, including whether to
 23 use such methodology as a basis for performance bo-
 24 nuses.

1 (c) IMPROVED PROVIDER EDUCATION AND TRAIN-
2 ING.—

3 (1) INCREASED FUNDING FOR ENHANCED EDU-
4 CATION AND TRAINING THROUGH MEDICARE INTEG-
5 RITY PROGRAM.—Section 1817(k)(4) (42 U.S.C.
6 1395i(k)(4)) is amended—

7 (A) in subparagraph (A), by striking “sub-
8 paragraph (B)” and inserting “subparagraphs
9 (B) and (C)”;

10 (B) in subparagraph (B), by striking “The
11 amount appropriated” and inserting “Subject
12 to subparagraph (C), the amount appro-
13 priated”; and

14 (C) by adding at the end the following new
15 subparagraph:

16 “(C) ENHANCED PROVIDER EDUCATION
17 AND TRAINING.—

18 “(i) IN GENERAL.—In addition to the
19 amount appropriated under subparagraph
20 (B), the amount appropriated under sub-
21 paragraph (A) for a fiscal year (beginning
22 with fiscal year 2004) is increased by
23 \$35,000,000.

24 “(ii) USE.—The funds made available
25 under this subparagraph shall be used only

1 to increase the conduct by medicare con-
 2 tractors of education and training of pro-
 3 viders of services, physicians, practitioners,
 4 and suppliers regarding billing, coding, and
 5 other appropriate items and may also be
 6 used to improve the accuracy, consistency,
 7 and timeliness of contractor responses to
 8 written and phone inquiries from providers
 9 of services, physicians, practitioners, and
 10 suppliers.”.

11 (2) TAILORING EDUCATION AND TRAINING FOR
 12 SMALL PROVIDERS OR SUPPLIERS.—

13 (A) IN GENERAL.—Section 1889, as added
 14 by subsection (a), is amended by adding at the
 15 end the following new subsection:

16 “(b) TAILORING EDUCATION AND TRAINING ACTIVI-
 17 TIES FOR SMALL PROVIDERS OR SUPPLIERS.—

18 “(1) IN GENERAL.—Insofar as a medicare con-
 19 tractor conducts education and training activities, it
 20 shall take into consideration the special needs of
 21 small providers of services or suppliers (as defined in
 22 paragraph (2)). Such education and training activi-
 23 ties for small providers of services and suppliers may
 24 include the provision of technical assistance (such as
 25 review of billing systems and internal controls to de-

1 termine program compliance and to suggest more ef-
 2 ficient and effective means of achieving such compli-
 3 ance).

4 “(2) SMALL PROVIDER OF SERVICES OR SUP-
 5 PLIER.—In this subsection, the term ‘small provider
 6 of services or supplier’ means—

7 “(A) an institutional provider of services
 8 with fewer than 25 full-time-equivalent employ-
 9 ees; or

10 “(B) a physician, practitioner, or supplier
 11 with fewer than 10 full-time-equivalent employ-
 12 ees.”.

13 (B) EFFECTIVE DATE.—The amendment
 14 made by subparagraph (A) shall take effect on
 15 January 1, 2004.

16 (d) ADDITIONAL PROVIDER EDUCATION PROVI-
 17 SIONS.—

18 (1) IN GENERAL.—Section 1889, as added by
 19 subsection (a) and as amended by subsection (c)(2),
 20 is amended by adding at the end the following new
 21 subsections:

22 “(c) ENCOURAGEMENT OF PARTICIPATION IN EDU-
 23 CATION PROGRAM ACTIVITIES.—A medicare contractor
 24 may not use a record of attendance at (or failure to at-
 25 tend) educational activities or other information gathered

1 during an educational program conducted under this sec-
 2 tion or otherwise by the Secretary to select or track pro-
 3 viders of services, physicians, practitioners, or suppliers
 4 for the purpose of conducting any type of audit or prepay-
 5 ment review.

6 “(d) CONSTRUCTION.—Nothing in this section or sec-
 7 tion 1893(g) shall be construed as providing for disclosure
 8 by a medicare contractor—

9 “(1) of the screens used for identifying claims
 10 that will be subject to medical review; or

11 “(2) of information that would compromise
 12 pending law enforcement activities or reveal findings
 13 of law enforcement-related audits.

14 “(e) DEFINITIONS.—For purposes of this section and
 15 section 1817(k)(4)(C), the term ‘medicare contractor’ in-
 16 cludes the following:

17 “(1) A medicare administrative contractor with
 18 a contract under section 1874A, a fiscal inter-
 19 mediary with a contract under section 1816, and a
 20 carrier with a contract under section 1842.

21 “(2) An eligible entity with a contract under
 22 section 1893.

23 Such term does not include, with respect to activities of
 24 a specific provider of services, physician, practitioner, or
 25 supplier an entity that has no authority under this title

1 or title XI with respect to such activities and such provider
 2 of services, physician, practitioner, or supplier.”.

3 (2) EFFECTIVE DATE.—The amendment made
 4 by paragraph (1) shall take effect on the date of en-
 5 actment of this Act.

6 **SEC. 532. ACCESS TO AND PROMPT RESPONSES FROM**
 7 **MEDICARE CONTRACTORS.**

8 (a) IN GENERAL.—Section 1874A, as added by sec-
 9 tion 521(a)(1) and as amended by section 531(b)(1), is
 10 amended by adding at the end the following new sub-
 11 section:

12 “(f) COMMUNICATING WITH BENEFICIARIES AND
 13 PROVIDERS.—

14 “(1) COMMUNICATION PROCESS.—The Sec-
 15 retary shall develop a process for medicare contrac-
 16 tors to communicate with beneficiaries and with pro-
 17 viders of services, physicians, practitioners, and sup-
 18 pliers under this title.

19 “(2) RESPONSE TO WRITTEN INQUIRIES.—Each
 20 medicare contractor (as defined in paragraph (5))
 21 shall provide general written responses (which may
 22 be through electronic transmission) in a clear, con-
 23 cise, and accurate manner to inquiries by bene-
 24 ficiaries, providers of services, physicians, practi-
 25 tioners, and suppliers concerning the programs

1 under this title within 45 business days of the date
2 of receipt of such inquiries.

3 “(3) RESPONSE TO TOLL-FREE LINES.—The
4 Secretary shall ensure that medicare contractors
5 provide a toll-free telephone number at which bene-
6 ficiaries, providers, physicians, practitioners, and
7 suppliers may obtain information regarding billing,
8 coding, claims, coverage, and other appropriate in-
9 formation under this title.

10 “(4) MONITORING OF CONTRACTOR RE-
11 SPONSES.—

12 “(A) IN GENERAL.—Each medicare con-
13 tractor shall, consistent with standards devel-
14 oped by the Secretary under subparagraph
15 (B)—

16 “(i) maintain a system for identifying
17 who provides the information referred to in
18 paragraphs (2) and (3); and

19 “(ii) monitor the accuracy, consist-
20 ency, and timeliness of the information so
21 provided.

22 “(B) DEVELOPMENT OF STANDARDS.—

23 “(i) IN GENERAL.—The Secretary
24 shall establish (and publish in the Federal
25 Register) standards regarding the accu-

1 racy, consistency, and timeliness of the in-
2 formation provided in response to inquiries
3 under this subsection. Such standards shall
4 be consistent with the performance require-
5 ments established under subsection (b)(3).

6 “(ii) EVALUATION.—In conducting
7 evaluations of individual medicare contrac-
8 tors, the Secretary shall consider the re-
9 sults of the monitoring conducted under
10 subparagraph (A) taking into account as
11 performance requirements the standards
12 established under clause (i). The Secretary
13 shall, in consultation with organizations
14 representing providers of services, sup-
15 pliers, and individuals entitled to benefits
16 under part A or enrolled under part B, or
17 both, establish standards relating to the
18 accuracy, consistency, and timeliness of the
19 information so provided.

20 “(C) DIRECT MONITORING.—Nothing in
21 this paragraph shall be construed as preventing
22 the Secretary from directly monitoring the ac-
23 curacy, consistency, and timeliness of the infor-
24 mation so provided.

1 “(5) MEDICARE CONTRACTOR DEFINED.—For
2 purposes of this subsection, the term ‘medicare con-
3 tractor’ has the meaning given such term in sub-
4 section (e)(3).”.

5 (b) EFFECTIVE DATE.—The amendment made by
6 subsection (a) shall take effect October 1, 2004.

7 (c) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated such sums as are nec-
9 essary to carry out section 1874A(f) of the Social Security
10 Act, as added by subsection (a).

11 **SEC. 533. RELIANCE ON GUIDANCE.**

12 (a) IN GENERAL.—Section 1871(d), as added by sec-
13 tion 502(a), is amended by adding at the end the following
14 new paragraph:

15 “(2) If—

16 “(A) a provider of services, physician, practi-
17 tioner, or other supplier follows written guidance
18 provided—

19 “(i) by the Secretary; or

20 “(ii) by a medicare contractor (as defined
21 in section 1889(e) and whether in the form of
22 a written response to a written inquiry under
23 section 1874A(f)(1) or otherwise) acting within
24 the scope of the contractor’s contract authority,

1 in response to a written inquiry with respect to the
2 furnishing of items or services or the submission of
3 a claim for benefits for such items or services;

4 “(B) the Secretary determines that—

5 “(i) the provider of services, physician,
6 practitioner, or supplier has accurately pre-
7 sented the circumstances relating to such items,
8 services, and claim to the Secretary or the con-
9 tractor in the written guidance; and

10 “(ii) there is no indication of fraud or
11 abuse committed by the provider of services,
12 physician, practitioner, or supplier against the
13 program under this title; and

14 “(C) the guidance was in error;

15 the provider of services, physician, practitioner, or supplier
16 shall not be subject to any penalty or interest under this
17 title (or the provisions of title XI insofar as they relate
18 to this title) relating to the provision of such items or serv-
19 ice or such claim if the provider of services, physician,
20 practitioner, or supplier reasonably relied on such guid-
21 ance. In applying this paragraph with respect to guidance
22 in the form of general responses to frequently asked ques-
23 tions, the Secretary retains authority to determine the ex-
24 tent to which such general responses apply to the par-
25 ticular circumstances of individual claims.”

1 (b) EFFECTIVE DATE.—The amendment made by
 2 subsection (a) shall apply to penalties imposed on or after
 3 the date of enactment of this Act.

4 **SEC. 534. MEDICARE PROVIDER OMBUDSMAN.**

5 (a) MEDICARE PROVIDER OMBUDSMAN.—Section
 6 1868 (42 U.S.C. 1395ee) is amended—

7 (1) by adding at the end of the heading the fol-
 8 lowing: “; MEDICARE PROVIDER OMBUDSMAN”;

9 (2) by inserting “PRACTICING PHYSICIANS AD-
 10 VISORY COUNCIL.—(1)” after “(a)”;

11 (3) in paragraph (1), as so redesignated under
 12 paragraph (2), by striking “in this section” and in-
 13 serting “in this subsection”;

14 (4) by redesignating subsections (b) and (c) as
 15 paragraphs (2) and (3), respectively; and

16 (5) by adding at the end the following new sub-
 17 section:

18 “(b) MEDICARE PROVIDER OMBUDSMAN.—

19 “(1) IN GENERAL.—By not later than 1 year
 20 after the date of enactment of the Prescription Drug
 21 and Medicare Improvement Act of 2003, the Sec-
 22 retary shall appoint a Medicare Provider Ombuds-
 23 man.

24 “(2) DUTIES.—The Medicare Provider Om-
 25 budsman shall—

“(A) provide assistance, on a confidential basis, to entities and individuals providing items and services, including covered drugs under part D, under this title with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

“(B) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

“(i) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is wide-

1 spread confusion in program administra-
2 tion), and

3 “(ii) recommendations to provide for
4 an appropriate and consistent response (in-
5 cluding not providing for audits) in cases
6 of self-identified overpayments by providers
7 of services and suppliers.

8 “(3) STAFF.—The Secretary shall provide the
9 Medicare Provider Ombudsman with appropriate
10 staff.”.

11 (b) FUNDING.—There are authorized to be appro-
12 priated to the Secretary (in appropriate part from the
13 Federal Hospital Insurance Trust Fund and the Federal
14 Supplementary Medical Insurance Trust Fund (including
15 the Prescription Drug Account)) to carry out the provi-
16 sions of subsection (b) of section 1868 of the Social Secu-
17 rity Act (42 U.S.C. 1395ee) (relating to the Medicare Pro-
18 vider Ombudsman), as added by subsection (a)(5), such
19 sums as are necessary for fiscal year 2004 and each suc-
20 ceeding fiscal year.

21 **SEC. 535. BENEFICIARY OUTREACH DEMONSTRATION PRO-**
22 **GRAMS.**

23 (a) DEMONSTRATION ON THE PROVISION OF ADVICE
24 AND ASSISTANCE TO MEDICARE BENEFICIARIES AT

1 LOCAL OFFICES OF THE SOCIAL SECURITY ADMINISTRA-
2 TION.—

3 (1) ESTABLISHMENT.—The Secretary shall es-
4 tablish a demonstration program (in this subsection
5 referred to as the “demonstration program”) under
6 which medicare specialists employed by the Depart-
7 ment of Health and Human Services provide advice
8 and assistance to medicare beneficiaries at the loca-
9 tion of existing local offices of the Social Security
10 Administration.

11 (2) LOCATIONS.—

12 (A) IN GENERAL.—The demonstration pro-
13 gram shall be conducted in at least 6 offices or
14 areas. Subject to subparagraph (B), in selecting
15 such offices and areas, the Secretary shall pro-
16 vide preference for offices with a high volume of
17 visits by medicare beneficiaries.

18 (B) ASSISTANCE FOR RURAL BENE-
19 FICIARIES.—The Secretary shall provide for the
20 selection of at least 2 rural areas to participate
21 in the demonstration program. In conducting
22 the demonstration program in such rural areas,
23 the Secretary shall provide for medicare special-
24 ists to travel among local offices in a rural area
25 on a scheduled basis.

1 (3) DURATION.—The demonstration program
2 shall be conducted over a 3-year period.

3 (4) EVALUATION AND REPORT.—

4 (A) EVALUATION.—The Secretary shall
5 provide for an evaluation of the demonstration
6 program. Such evaluation shall include an anal-
7 ysis of—

8 (i) utilization of, and beneficiary satis-
9 faction with, the assistance provided under
10 the program; and

11 (ii) the cost-effectiveness of providing
12 beneficiary assistance through out-sta-
13 tioning medicare specialists at local social
14 security offices.

15 (B) REPORT.—The Secretary shall submit
16 to Congress a report on such evaluation and
17 shall include in such report recommendations
18 regarding the feasibility of permanently out-sta-
19 tioning Medicare specialists at local social secu-
20 rity offices.

21 (b) DEMONSTRATION ON PROVIDING PRIOR DETER-
22 MINATIONS.—

23 (1) ESTABLISHMENT.—By not later than 1
24 year after the date of enactment of this Act, the
25 Secretary shall establish a demonstration project to

1 test the administrative feasibility of providing a
2 process for medicare beneficiaries and entities and
3 individuals furnishing such beneficiaries with items
4 and services under title XVIII of the Social Security
5 Act program to make a request for, and receive, a
6 determination (after an advance beneficiary notice is
7 issued with respect to the item or service involved
8 but before such item or service is furnished to the
9 beneficiary) as to whether the item or service is cov-
10 ered under such title consistent with the applicable
11 requirements of section 1862(a)(1)(A) of such Act
12 (42 U.S.C. 1395y(a)(1)(A)) (relating to medical ne-
13 cessity).

14 (2) EVALUATION AND REPORT.—

15 (A) EVALUATION.—The Secretary shall
16 provide for an evaluation of the demonstration
17 program conducted under paragraph (1).

18 (B) REPORT.—By not later than January
19 1, 2006, the Secretary shall submit to Congress
20 a report on such evaluation together with rec-
21 ommendations for such legislation and adminis-
22 trative actions as the Secretary considers appro-
23 priate. *1/1/2006*

1 **Subtitle E—Review, Recovery, and** 2 **Enforcement Reform**

3 **SEC. 541. PREPAYMENT REVIEW.**

4 (a) IN GENERAL.—Section 1874A, as added by sec-
 5 tion 521(a)(1) and as amended by sections 531(b)(1) and
 6 532(a), is amended by adding at the end the following new
 7 subsection:

8 “(g) CONDUCT OF PREPAYMENT REVIEW.—

9 “(1) STANDARDIZATION OF RANDOM PREPAY-
 10 MENT REVIEW.—A medicare administrative con-
 11 tractor shall conduct random prepayment review
 12 only in accordance with a standard protocol for ran-
 13 dom prepayment audits developed by the Secretary.

14 “(2) LIMITATIONS ON INITIATION OF NON-
 15 RANDOM PREPAYMENT REVIEW.—A medicare admin-
 16 istrative contractor may not initiate nonrandom pre-
 17 payment review of a provider of services, physician,
 18 practitioner, or supplier based on the initial identi-
 19 fication by that provider of services, physician, prac-
 20 titioner, or supplier of an improper billing practice
 21 unless there is a likelihood of sustained or high level
 22 of payment error (as defined by the Secretary).

23 “(3) TERMINATION OF NONRANDOM PREPAY-
 24 MENT REVIEW.—The Secretary shall establish proto-
 25 cols or standards relating to the termination, includ-

ing termination dates, of nonrandom prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.

“(4) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review. In the case of a provider of services, physician, practitioner, or supplier with respect to which amounts were previously overpaid, nothing in this subsection shall be construed as limiting the ability of a medicare administrative contractor to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

“(5) RANDOM PREPAYMENT REVIEW DEFINED.—For purposes of this subsection, the term ‘random prepayment review’ means a demand for the production of records or documentation absent cause with respect to a claim.”.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a)

1 shall take effect on the date of enactment of this
2 Act.

3 (2) DEADLINE FOR PROMULGATION OF CER-
4 TAIN REGULATIONS.—The Secretary shall first issue
5 regulations under section 1874A(g) of the Social Se-
6 curity Act, as added by subsection (a), by not later
7 than 1 year after the date of enactment of this Act.

8 (3) APPLICATION OF STANDARD PROTOCOLS
9 FOR RANDOM PREPAYMENT REVIEW.—Section
10 1874A(g)(1) of the Social Security Act, as added by
11 subsection (a), shall apply to random prepayment re-
12 views conducted on or after such date (not later
13 than 1 year after the date of enactment of this Act)
14 as the Secretary shall specify. The Secretary shall
15 develop and publish the standard protocol under
16 such section by not later than 1 year after the date
17 of enactment of this Act.

18 **SEC. 542. RECOVERY OF OVERPAYMENTS.**

19 (a) IN GENERAL.—Section 1874A, as added by sec-
20 tion 521(a)(1) and as amended by sections 531(b)(1),
21 532(a), and 541(a), is amended by adding at the end the
22 following new subsection:

23 “(h) RECOVERY OF OVERPAYMENTS.—

24 “(1) USE OF REPAYMENT PLANS.—

1 “(A) IN GENERAL.—If the repayment,
2 within the period otherwise permitted by a pro-
3 vider of services, physician, practitioner, or
4 other supplier, of an overpayment under this
5 title meets the standards developed under sub-
6 paragraph (B), subject to subparagraph (C),
7 and the provider, physician, practitioner, or
8 supplier requests the Secretary to enter into a
9 repayment plan with respect to such overpay-
10 ment, the Secretary shall enter into a plan with
11 the provider, physician, practitioner, or supplier
12 for the offset or repayment (at the election of
13 the provider, physician, practitioner, or sup-
14 plier) of such overpayment over a period of at
15 least 1 year, but not longer than 3 years. Inter-
16 est shall accrue on the balance through the pe-
17 riod of repayment. The repayment plan shall
18 meet terms and conditions determined to be ap-
19 propriate by the Secretary.

20 “(B) DEVELOPMENT OF STANDARDS.—
21 The Secretary shall develop standards for the
22 recovery of overpayments. Such standards
23 shall— ~~be established~~

24 “(i) include a requirement that the
25 Secretary take into account (and weigh in

1 favor of the use of a repayment plan) the
2 reliance (as described in section
3 1871(d)(2)) by a provider of services, phy-
4 sician, practitioner, and supplier on guid-
5 ance when determining whether a repay-
6 ment plan should be offered; and

7 “(ii) provide for consideration of the
8 financial hardship imposed on a provider of
9 services, physician, practitioner, or supplier
10 in considering such a repayment plan.

11 In developing standards with regard to financial
12 hardship with respect to a provider of services,
13 physician, practitioner, or supplier, the Sec-
14 retary shall take into account the amount of the
15 proposed recovery as a proportion of payments
16 made to that provider, physician, practitioner,
17 or supplier.

18 “(C) EXCEPTIONS.—Subparagraph (A)
19 shall not apply if—

20 “(i) the Secretary has reason to sus-
21 pect that the provider of services, physi-
22 cian, practitioner, or supplier may file for
23 bankruptcy or otherwise cease to do busi-
24 ness or discontinue participation in the
25 program under this title; or

1 “(ii) there is an indication of fraud or
2 EDUCATION abuse committed against the program.

3 “(D) IMMEDIATE COLLECTION IF VIOLA-
4 TION OF REPAYMENT PLAN.—If a provider of
5 services, physician, practitioner, or supplier fails
6 to make a payment in accordance with a repay-
7 ment plan under this paragraph, the Secretary
8 may immediately seek to offset or otherwise re-
9 cover the total balance outstanding (including
10 applicable interest) under the repayment plan.

11 “(E) RELATION TO NO FAULT PROVI-
12 SION.—Nothing in this paragraph shall be con-
13 strued as affecting the application of section
14 1870(c) (relating to no adjustment in the cases
15 of certain overpayments).

16 “(2) LIMITATION ON RECOUPMENT.—

17 “(A) NO RECOUPMENT UNTIL RECONSID-
18 ERATION EXERCISED.—In the case of a pro-
19 vider of services, physician, practitioner, or sup-
20 plier that is determined to have received an
21 overpayment under this title and that seeks a
22 reconsideration of such determination by a
23 qualified independent contractor under section
24 1869(c), the Secretary may not take any action
25 (or authorize any other person, including any

1 Medicare contractor, as defined in subpara-
 2 graph (C)) to recoup the overpayment until the
 3 date the decision on the reconsideration has
 4 been rendered.

5 “(B) PAYMENT OF INTEREST.—

6 “(i) RETURN OF RECOUPED AMOUNT
 7 WITH INTEREST IN CASE OF REVERSAL.—

8 Insofar as such determination on appeal
 9 against the provider of services, physician,
 10 practitioner, or supplier is later reversed,
 11 the Secretary shall provide for repayment
 12 of the amount recouped plus interest for
 13 the period in which the amount was re-
 14 couped.

15 “(ii) INTEREST IN CASE OF AFFIRMA-
 16 TION.—Insofar as the determination on
 17 such appeal is against the provider of serv-
 18 ices, physician, practitioner, or supplier, in-
 19 terest on the overpayment shall accrue on
 20 and after the date of the original notice of
 21 overpayment.

22 “(iii) RATE OF INTEREST.—The rate
 23 of interest under this subparagraph shall
 24 be the rate otherwise applicable under this
 25 title in the case of overpayments.

1 “(C) MEDICARE CONTRACTOR DEFINED.—

2 For purposes of this subsection, the term ‘medi-
3 care contractor’ has the meaning given such
4 term in section 1889(e).

5 “(3) PAYMENT AUDITS.—

6 “(A) WRITTEN NOTICE FOR POST-PAY-
7 MENT AUDITS.—Subject to subparagraph (C), if
8 a medicare contractor decides to conduct a
9 post-payment audit of a provider of services,
10 physician, practitioner, or supplier under this
11 title, the contractor shall provide the provider of
12 services, physician, practitioner, or supplier
13 with written notice (which may be in electronic
14 form) of the intent to conduct such an audit.

15 “(B) EXPLANATION OF FINDINGS FOR ALL
16 AUDITS.—Subject to subparagraph (C), if a
17 medicare contractor audits a provider of serv-
18 ices, physician, practitioner, or supplier under
19 this title, the contractor shall—

20 ~~and shall~~“(i) give the provider of services, phy-
21 sician, practitioner, or supplier a full re-
22 view and explanation of the findings of the
23 audit in a manner that is understandable
24 to the provider of services, physician, prac-
25 titioner, or supplier and permits the devel-

1 opment of an appropriate corrective action
2 plan;

3 “(ii) inform the provider of services,
4 physician, practitioner, or supplier of the
5 appeal rights under this title as well as
6 consent settlement options (which are at
7 the discretion of the Secretary); and

8 “(iii) give the provider of services,
9 physician, practitioner, or supplier an op-
10 portunity to provide additional information
11 to the contractor.

12 “(C) EXCEPTION.—Subparagraphs (A)
13 and (B) shall not apply if the provision of no-
14 tice or findings would compromise pending law
15 enforcement activities, whether civil or criminal,
16 or reveal findings of law enforcement-related
17 audits.

18 “(4) NOTICE OF OVER-UTILIZATION OF
19 CODES.—The Secretary shall establish, in consulta-
20 tion with organizations representing the classes of
21 providers of services, physicians, practitioners, and
22 suppliers, a process under which the Secretary pro-
23 vides for notice to classes of providers of services,
24 physicians, practitioners, and suppliers served by a
25 medicare contractor in cases in which the contractor

has identified that particular billing codes may be overutilized by that class of providers of services, physicians, practitioners, or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

“(5) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare administrative contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

“(6) CONSENT SETTLEMENT REFORMS.—

“(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

“(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services, physician, practitioner, or supplier a consent settlement, the Secretary shall—

“(i) communicate to the provider of services, physician, practitioner, or supplier in a nonthreatening manner that, based on a review of the medical records requested by the Secretary, a preliminary evaluation

1 of those records indicates that there would
2 be an overpayment; and

3 “(ii) provide for a 45-day period dur-
4 ing which the provider of services, physi-
5 cian, practitioner, or supplier may furnish
6 additional information concerning the med-
7 ical records for the claims that had been
8 reviewed.

9 “(C) CONSENT SETTLEMENT OFFER.—The
10 Secretary shall review any additional informa-
11 tion furnished by the provider of services, physi-
12 cian, practitioner, or supplier under subpara-
13 graph (B)(ii). Taking into consideration such
14 information, the Secretary shall determine if
15 there still appears to be an overpayment. If so,
16 the Secretary—

17 “(i) shall provide notice of such deter-
18 mination to the provider of services, physi-
19 cian, practitioner, or supplier, including an
20 explanation of the reason for such deter-
21 mination; and

22 “(ii) in order to resolve the overpay-
23 ment, may offer the provider of services,
24 physician, practitioner, or supplier—

“(I) the opportunity for a statistically valid random sample; or

“(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

“(D) CONSENT SETTLEMENT DEFINED.—

For purposes of this paragraph, the term ‘consent settlement’ means an agreement between the Secretary and a provider of services, physician, practitioner, or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services, physician, practitioner, or supplier agrees not to appeal the claims involved.”.

(b) EFFECTIVE DATES AND DEADLINES.—

(1) Not later than 1 year after the date of enactment of this Act, the Secretary shall first—

(A) develop standards for the recovery of overpayments under section 1874A(h)(1)(B) of the Social Security Act, as added by subsection (a);

(B) establish the process for notice of overutilization of billing codes under section

1 1874A(h)(4) of the Social Security Act, as
2 added by subsection (a); and

3 (C) establish a standard methodology for
4 selection of sample claims for abnormal billing
5 patterns under section 1874A(h)(5) of the So-
6 cial Security Act, as added by subsection (a).

7 (2) Section 1874A(h)(2) of the Social Security
8 Act, as added by subsection (a), shall apply to ac-
9 tions taken after the date that is 1 year after the
10 date of enactment of this Act.

11 (3) Section 1874A(h)(3) of the Social Security
12 Act, as added by subsection (a), shall apply to audits
13 initiated after the date of enactment of this Act.

14 (4) Section 1874A(h)(6) of the Social Security
15 Act, as added by subsection (a), shall apply to con-
16 sent settlements entered into after the date of enact-
17 ment of this Act.

18 **SEC. 543. PROCESS FOR CORRECTION OF MINOR ERRORS**
19 **AND OMISSIONS ON CLAIMS WITHOUT PUR-**
20 **SUING APPEALS PROCESS.**

21 (a) IN GENERAL.—The Secretary shall develop, in
22 consultation with appropriate medicare contractors (as de-
23 fined in section 1889(e) of the Social Security Act, as
24 added by section 531(d)(1)) and representatives of pro-
25 viders of services, physicians, practitioners, facilities, and

1 suppliers, a process whereby, in the case of minor errors
2 or omissions (as defined by the Secretary) that are de-
3 tected in the submission of claims under the programs
4 under title XVIII of such Act, a provider of services, phy-
5 sician, practitioner, facility, or supplier is given an oppor-
6 tunity to correct such an error or omission without the
7 need to initiate an appeal. Such process shall include the
8 ability to resubmit corrected claims.

9 (b) DEADLINE.—Not later than 1 year after the date
10 of enactment of this Act, the Secretary shall first develop
11 the process under subsection (a).

12 **SEC. 544. AUTHORITY TO WAIVE A PROGRAM EXCLUSION.**

13 The first sentence of section 1128(c)(3)(B) (42
14 U.S.C. 1320a-7(c)(3)(B)) is amended to read as follows:
15 “Subject to subparagraph (G), in the case of an exclusion
16 under subsection (a), the minimum period of exclusion
17 shall be not less than 5 years, except that, upon the re-
18 quest of an administrator of a Federal health care pro-
19 gram (as defined in section 1128B(f)) who determines
20 that the exclusion would impose a hardship on bene-
21 ficiaries of that program, the Secretary may, after con-
22 sulting with the Inspector General of the Department of
23 Health and Human Services, waive the exclusion under
24 subsection (a)(1), (a)(3), or (a)(4) with respect to that
25 program in the case of an individual or entity that is the

1 sole community physician or sole source of essential spe-
 2 cialized services in a community.”.

3 **Subtitle F—Other Improvements**

4 **SEC. 551. INCLUSION OF ADDITIONAL INFORMATION IN NO-** 5 **TICES TO BENEFICIARIES ABOUT SKILLED** 6 **NURSING FACILITY AND HOSPITAL BENE-** 7 **FITS.**

8 (a) IN GENERAL.—The Secretary shall provide that
 9 in medicare beneficiary notices provided (under section
 10 1806(a) of the Social Security Act, 42 U.S.C. 1395b-7(a))
 11 with respect to the provision of post-hospital extended care
 12 services and inpatient hospital services under part A of
 13 title XVIII of the Social Security Act, there shall be in-
 14 cluded information on the number of days of coverage of
 15 such services remaining under such part for the medicare
 16 beneficiary and spell of illness involved.

17 (b) EFFECTIVE DATE.—Subsection (a) shall apply to
 18 notices provided during calendar quarters beginning more
 19 than 6 months after the date of enactment of this Act.

20 **SEC. 552. INFORMATION ON MEDICARE-CERTIFIED** 21 **SKILLED NURSING FACILITIES IN HOSPITAL** 22 **DISCHARGE PLANS.**

23 (a) AVAILABILITY OF DATA.—The Secretary shall
 24 publicly provide information that enables hospital dis-
 25 charge planners, medicare beneficiaries, and the public to

1 identify skilled nursing facilities that are participating in
2 the medicare program.

3 (b) INCLUSION OF INFORMATION IN CERTAIN HOS-
4 PITAL DISCHARGE PLANS.—

5 (1) IN GENERAL.—Section 1861(ee)(2)(D) (42
6 U.S.C. 1395x(ee)(2)(D)) is amended—

7 (A) by striking “hospice services” and in-
8 serting “hospice care and post-hospital ex-
9 tended care services”; and

10 (B) by inserting before the period at the
11 end the following: “and, in the case of individ-
12 uals who are likely to need post-hospital ex-
13 tended care services, the availability of such
14 services through facilities that participate in the
15 program under this title and that serve the area
16 in which the patient resides”.

17 (2) EFFECTIVE DATE.—The amendments made
18 by paragraph (1) shall apply to discharge plans
19 made on or after such date as the Secretary shall
20 specify, but not later than 6 months after the date
21 the Secretary provides for availability of information
22 under subsection (a).

1 **SEC. 553. EVALUATION AND MANAGEMENT DOCUMENTA-**
2 **TION GUIDELINES CONSIDERATION.**

3 The Secretary shall ensure, before making changes
4 in documentation guidelines for, or clinical examples of,
5 or codes to report evaluation and management physician
6 services under title XVIII of Social Security Act, that the
7 process used in developing such guidelines, examples, or
8 codes was widely consultative among physicians, reflects
9 a broad consensus among specialties, and would allow
10 verification of reported and furnished services.

11 **SEC. 554. COUNCIL FOR TECHNOLOGY AND INNOVATION.**

12 Section 1868 (42 U.S.C. 1395ee), as amended by sec-
13 tion 534(a), is amended by adding at the end the following
14 new subsection:

15 “(c) COUNCIL FOR TECHNOLOGY AND INNOVA-
16 TION.—

17 “(1) ESTABLISHMENT.—The Secretary shall es-
18 tablish a Council for Technology and Innovation
19 within the Centers for Medicare & Medicaid Services
20 (in this section referred to as ‘CMS’).

21 “(2) COMPOSITION.—The Council shall be com-
22 posed of senior CMS staff and clinicians and shall
23 be chaired by the Executive Coordinator for Tech-
24 nology and Innovation (appointed or designated
25 under paragraph (4)).

“(3) DUTIES.—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

“(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this title.”.

SEC. 555. TREATMENT OF CERTAIN DENTAL CLAIMS.

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by adding after subsection (g) the following new subsection:

“(h)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supple-

1 mental or secondary coverage to individuals also entitled
 2 to services under this title shall not require a medicare
 3 claims determination under this title for dental benefits
 4 specifically excluded under subsection (a)(12) as a condi-
 5 tion of making a claims determination for such benefits
 6 under the group health plan.

7 “(2) A group health plan may require a claims deter-
 8 mination under this title in cases involving or appearing
 9 to involve inpatient dental hospital services or dental serv-
 10 ices expressly covered under this title pursuant to actions
 11 taken by the Secretary.”.

12 (b) EFFECTIVE DATE.—The amendment made by
 13 subsection (a) shall take effect on the date that is 60 days
 14 after the date of enactment of this Act.

15 **TITLE VI—OTHER PROVISIONS**

16 **SEC. 601. INCREASE IN MEDICAID DSH ALLOTMENTS FOR** 17 **FISCAL YEARS 2004 AND 2005.**

18 (a) IN GENERAL.—Section 1923(f)(4) (42 U.S.C.
 19 1396r-4(f)(4)) is amended—

20 (1) in the paragraph heading, by striking “FIS-
 21 CAL YEARS 2001 AND 2002” and inserting “CERTAIN
 22 FISCAL YEARS”;

23 (2) in subparagraph (A)—

24 (A) in clause (i)—

(i) by striking “paragraph (2)” and inserting “paragraphs (2) and (3)”; and

(ii) by striking “and” at the end;

(B) in clause (ii), by striking the period and inserting a semicolon; and

(C) by adding at the end the following:

“(iii) for fiscal year 2004, shall be the DSH allotment determined under paragraph (3) for that fiscal year increased by the amount equal to the product of 0.50 and the difference between—

“(I) the amount that the DSH allotment would be if the DSH allotment for the State determined under clause (ii) were increased, subject to subparagraph (B) and paragraph (5), by the percentage change in the Consumer Price Index for all urban consumers (all items; U.S. city average)

for each of fiscal years 2002 and 2003; and

“(II) the DSH allotment determined under paragraph (3) for the State for fiscal year 2004; and

1 “(iv) for fiscal year 2005, shall be the
 2 DSH allotment determined under para-
 3 graph (3) for that fiscal year increased by
 4 the amount equal to the product of 0.50
 5 and the difference between—

6 “(I) the amount that the DSH
 7 allotment would be if the DSH allot-
 8 ment for the State determined under
 9 clause (ii) were increased, subject to
 10 subparagraph (B) and paragraph (5),
 11 by the percentage change in the Con-
 12 sumer Price Index for all urban con-
 13 sumers (all items; U.S. city average)
 14 for each of fiscal years 2002, 2003,
 15 and 2004; and

16 “(II) the DSH allotment deter-
 17 mined under paragraph (3) for the
 18 State for fiscal year 2005.”; and

19 (3) in subparagraph (C)—

20 (A) in the subparagraph heading, by strik-
 21 ing “AFTER FISCAL YEAR 2002” and inserting
 22 “FOR OTHER FISCAL YEARS”; and

23 (B) by striking “2003 or” and inserting
 24 “2003, fiscal year 2006, or”.

1 (b) DSH ALLOTMENT FOR THE DISTRICT OF CO-
 2 LUMBIA.—Section 1923(f)(4) (42 U.S.C. 1396r-4(f)(4)),
 3 as amended by paragraph (1), is amended—

4 (1) in subparagraph (A), by inserting “and ex-
 5 cept as provided in subparagraph (C)” after “para-
 6 graph (2)”;

7 (2) by redesignating subparagraph (C) as sub-
 8 paragraph (D); and

9 (3) by inserting after subparagraph (B) the fol-
 10 lowing:

11 “(C) DSH ALLOTMENT FOR THE DISTRICT
 12 OF COLUMBIA.—

13 “(i) IN GENERAL.—Notwithstanding
 14 subparagraph (A), the DSH allotment for
 15 the District of Columbia for fiscal year
 16 2004, shall be determined by substituting
 17 “49” for “32” in the item in the table con-
 18 tained in paragraph (2) with respect to the
 19 DSH allotment for FY 00 (fiscal year
 20 2000) for the District of Columbia, and
 21 then increasing such allotment, subject to
 22 subparagraph (B) and paragraph (5), by
 23 the percentage change in the Consumer
 24 Price Index for all urban consumers (all

1 items; U.S. city average) for each of fiscal
 2 years 2000, 2001, 2002, and 2003.

3 “(ii) NO APPLICATION TO ALLOT-
 4 MENTS AFTER FISCAL YEAR 2004.—The
 5 DSH allotment for the District of Colum-
 6 bia for fiscal year 2003, fiscal year 2005,
 7 or any succeeding fiscal year shall be de-
 8 termined under paragraph (3) without re-
 9 gard to the DSH allotment determined
 10 under clause (i).”.

11 (c) CONFORMING AMENDMENT.—Section 1923(f)(3)
 12 of such Act (42 U.S.C. 1396r-4(f)(3)) is amended by in-
 13 serting “, paragraph (4),” after “subparagraph (B)”.

14 (d) URBAN HEALTH PROVIDER ADJUSTMENT.—

15 (1) IN GENERAL.—Beginning with fiscal year
 16 2004, notwithstanding section 1923(f) of the Social
 17 Security Act (42 U.S.C. 1396r-4(f)) and subject to
 18 paragraph (3), with respect to a State, payment ad-
 19 justments made under title XIX of the Social Secu-
 20 rity Act (42 U.S.C. 1396 et seq.) to a hospital de-
 21 scribed in paragraph (2) shall be made without re-
 22 gard to the DSH allotment limitation for the State
 23 determined under section 1923(f) of that Act (42
 24 U.S.C. 1396r-4(f)).

(2) HOSPITAL DESCRIBED.—A hospital is described in this paragraph if the hospital—

(A) is owned or operated by a State (as defined for purposes of title XIX of the Social Security Act), or by an instrumentality or a municipal governmental unit within a State (as so defined) as of January 1, 2003; and

(B) is located in Marion County, Indiana.

(3) LIMITATION.—The payment adjustment described in paragraph (1) for fiscal year 2004 and each fiscal year thereafter shall not exceed 175 percent of the costs of furnishing hospital services described in section 1923(g)(1)(A) of the Social Security Act (42 U.S.C. 1396r-4(g)(1)(A)).

SEC. 602. INCREASE IN FLOOR FOR TREATMENT AS AN EXTREMELY LOW DSH STATE UNDER THE MEDICAID PROGRAM FOR FISCAL YEARS 2004 AND 2005.

(a) IN GENERAL.—Section 1923(f)(5) (42 U.S.C. 1396r-4(f)(5)) is amended—

(1) by striking “In the case of” and inserting the following:

“(A) IN GENERAL.—In the case of”; and

(2) by adding at the end the following:

1 “(B) INCREASE IN FLOOR FOR FISCAL
2 YEARS 2004 AND 2005.—

3 “(i) FISCAL YEAR 2004.—In the case
4 of a State in which the total expenditures
5 under the State plan (including Federal
6 and State shares) for disproportionate
7 share hospital adjustments under this sec-
8 tion for fiscal year 2000, as reported to the
9 Administrator of the Centers for Medicare
10 & Medicaid Services as of August 31,
11 2003, is greater than 0 but less than 3
12 percent of the State’s total amount of ex-
13 penditures under the State plan for med-
14 ical assistance during the fiscal year, the
15 DSH allotment for fiscal year 2004 shall
16 be increased to 3 percent of the State’s
17 total amount of expenditures under such
18 plan for such assistance during such fiscal
19 year.

20 “(ii) FISCAL YEAR 2005.—In the case
21 of a State in which the total expenditures
22 under the State plan (including Federal
23 and State shares) for disproportionate
24 share hospital adjustments under this sec-
25 tion for fiscal year 2001, as reported to the

1 Administrator of the Centers for Medicare
 2 & Medicaid Services as of August 31,
 3 2004, is greater than 0 but less than 3
 4 percent of the State's total amount of ex-
 5 penditures under the State plan for med-
 6 ical assistance during the fiscal year, the
 7 DSH allotment for fiscal year 2005 shall
 8 be the DSH allotment determined for the
 9 State for fiscal year 2004 (under clause (i)
 10 or paragraph (4) (as applicable)), in-
 11 creased by the percentage change in the
 12 consumer price index for all urban con-
 13 sumers (all items; U.S. city average) for
 14 fiscal year 2004.

15 “(iii) NO APPLICATION TO ALLOT-
 16 MENTS AFTER FISCAL YEAR 2005.—The
 17 DSH allotment for any State for fiscal
 18 year 2006 or any succeeding fiscal year
 19 shall be determined under this subsection
 20 without regard to the DSH allotments de-
 21 termined under this subparagraph.”

22 (b) ALLOTMENT ADJUSTMENT.—

23 (1) IN GENERAL.—Section 1923(f) of the Social
 24 Security Act (42 U.S.C. 1396r-4(f)) is amended—

1 (A) by redesignating paragraph (6) as
2 paragraph (7); and

3 (B) by inserting after paragraph (5) the
4 following:

5 “(6) ALLOTMENT ADJUSTMENT.—Only with re-
6 spect to fiscal year 2004 or 2005, if a statewide
7 waiver under section 1115 that was implemented on
8 January 1, 1994, is revoked or terminated before
9 the end of either such fiscal year, the Secretary
10 shall—

11 “(A) permit the State whose waiver was
12 revoked or terminated to submit an amendment
13 to its State plan that would describe the meth-
14 odology to be used by the State (after the effec-
15 tive date of such revocation or termination) to
16 identify and make payments to disproportionate
17 share hospitals, including children’s hospitals
18 and institutions for mental diseases or other
19 mental health facilities (other than State-owned
20 institutions or facilities), on the basis of the
21 proportion of patients served by such hospitals
22 that are low-income patients with special needs;
23 and

24 “(B) provide for purposes of this sub-
25 section for computation of an appropriate DSH

allotment for the State for fiscal year 2004 or 2005 (or both) that provides for the maximum amount (permitted consistent with paragraph (3)(B)(ii)) that does not result in greater expenditures under this title than would have been made if such waiver had not been revoked or terminated.”.

(2) TREATMENT OF INSTITUTIONS FOR MENTAL DISEASES.—Section 1923(h)(1) of the Social Security Act (42 U.S.C. 1396r-4(h)(1)) is amended—

(A) in paragraph (1), in the matter preceding subparagraph (A), by inserting “(subject to paragraph (3))” after “the lesser of the following”; and

(B) by adding at the end the following new paragraph:

“(3) SPECIAL RULE.—The limitation of paragraph (1) shall not apply in the case of a State to which subsection (f)(6) applies.”.

(3) APPLICATION TO HAWAII.—Section 1923(f) (42 U.S.C. 1396r-4(f)), as amended by paragraph (1), is amended—

(A) by redesignating paragraph (7) as paragraph (8); and

1 (B) by inserting after paragraph (6), the
2 following:

3 “(7) TREATMENT OF HAWAII AS A LOW-DSH
4 STATE.—The Secretary shall compute a DSH allot-
5 ment for the State of Hawaii for each of fiscal years
6 2004 and 2005 in the same manner as DSH allot-
7 ments are determined with respect to those States to
8 which paragraph (5) applies (but without regard to
9 the requirement under such paragraph that total ex-
10 penditures under the State plan for disproportionate
11 share hospital adjustments for any fiscal year ex-
12 ceeds 0).”.

13 **SEC. 603. INCREASED REPORTING REQUIREMENTS TO EN-**
14 **SURE THE APPROPRIATENESS OF PAYMENT**
15 **ADJUSTMENTS TO DISPROPORTIONATE**
16 **SHARE HOSPITALS UNDER THE MEDICAID**
17 **PROGRAM.**

18 Section 1923 (42 U.S.C. 1396r-4) is amended by
19 adding at the end the following new subsection:

20 “(j) ANNUAL REPORTS REGARDING PAYMENT AD-
21 JUSTMENTS.—With respect to fiscal year 2004 and each
22 fiscal year thereafter, the Secretary shall require a State,
23 as a condition of receiving a payment under section
24 1903(a)(1) with respect to a payment adjustment made
25 under this section, to submit an annual report that—

“(1) identifies each disproportionate share hospital that received a payment adjustment under this section for the preceding fiscal year and the amount of the payment adjustment made to such hospital for the preceding fiscal year; and

“(2) includes such other information as the Secretary determines necessary to ensure the appropriateness of the payment adjustments made under this section for the preceding fiscal year.”.

**SEC. 604. CLARIFICATION OF INCLUSION OF INPATIENT
DRUG PRICES CHARGED TO CERTAIN PUBLIC
HOSPITALS IN THE BEST PRICE EXEMPTIONS
FOR THE MEDICAID DRUG REBATE PROGRAM.**

(a) IN GENERAL.—Section 1927(c)(1)(C)(i)(I) of the Social Security Act (42 U.S.C. 1396r-8(e)(1)(C)(i)(I)) is amended by inserting before the semicolon the following: “(including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act)”.

(b) ANTI-DIVERSION PROTECTION.—Section 1927(e)(1)(C) of the Social Security Act (42 U.S.C. 1396r-8(e)(1)(C)) is amended by adding at the end the following:

1 “(iii) APPLICATION OF AUDITING AND
 2 RECORDKEEPING REQUIREMENTS.—With
 3 respect to a covered entity described in
 4 section 340B(a)(4)(L) of the Public Health
 5 Service Act, any drug purchased for inpa-
 6 tient use shall be subject to the auditing
 7 and recordkeeping requirements described
 8 in section 340B(a)(5)(C) of the Public
 9 Health Service Act.”.

10 (c) EFFECTIVE DATE.—The amendments made by
 11 this section take effect on October 1, 2003.

12 **SEC. 605. ASSISTANCE WITH COVERAGE OF LEGAL IMMI-**
 13 **GRANTS UNDER THE MEDICAID PROGRAM**
 14 **AND SCHIP.**

15 (a) MEDICAID PROGRAM.—Section 1903(v) (42
 16 U.S.C. 1396b(v)) is amended—

17 (1) in paragraph (1), by striking “paragraph
 18 (2)” and inserting “paragraphs (2) and (4)”; and

19 (2) by adding at the end the following new
 20 paragraph:

21 “(4)(A) With respect to any or all of fiscal years 2005
 22 through 2007, a State may elect (in a plan amendment
 23 under this title) to provide medical assistance under this
 24 title (including under a waiver authorized by the Sec-
 25 retary) for aliens who are lawfully residing in the United

1 States (including battered aliens described in section
 2 431(c) of such Act) and who are otherwise eligible for such
 3 assistance, within either or both of the following eligibility
 4 categories:

5 “(i) PREGNANT WOMEN.—Women during preg-
 6 nancy (and during the 60-day period beginning on
 7 the last day of the pregnancy).

8 “(ii) CHILDREN.—Children (as defined under
 9 such plan), including optional targeted low-income
 10 children described in section 1905(u)(2)(B).

11 “(B)(i) In the case of a State that has elected to pro-
 12 vide medical assistance to a category of aliens under sub-
 13 paragraph (A), no debt shall accrue under an affidavit of
 14 support against any sponsor of such an alien on the basis
 15 of provision of assistance to such category and the cost
 16 of such assistance shall not be considered as an unreim-
 17 bursed cost.

18 “(ii) The provisions of sections 401(a), 402(b), 403,
 19 and 421 of the Personal Responsibility and Work Oppor-
 20 tunity Reconciliation Act of 1996 shall not apply to a
 21 State that makes an election under subparagraph (A).”.

22 (b) SCHIP.—Section 2107(e)(1) (42 U.S.C.
 23 1397gg(e)(1)) is amended by redesignating subparagraphs
 24 (C) and (D) as subparagraph (D) and (E), respectively,

1 and by inserting after subparagraph (B) the following new
2 subparagraph:

3 “(C) Section 1903(v)(4) (relating to op-
4 tional coverage of categories of permanent resi-
5 dent alien children), but only if the State has
6 elected to apply such section to the category of
7 children under title XIX and only with respect
8 to any or all of fiscal years 2005 through
9 2007.”.

10 **SEC. 606. ESTABLISHMENT OF CONSUMER OMBUDSMAN AC-**
11 **COUNT.**

12 (a) IN GENERAL.—Section 1817 (42 U.S.C. 1395i)
13 is amended by adding at the end the following new sub-
14 section:

15 “(i) CONSUMER OMBUDSMAN ACCOUNT.—

16 “(1) ESTABLISHMENT.—There is hereby estab-
17 lished in the Trust Fund an expenditure account to
18 be known as the ‘Consumer Ombudsman Account’
19 (in this subsection referred to as the ‘Account’).

20 “(2) APPROPRIATED AMOUNTS TO ACCOUNT
21 FOR HEALTH INSURANCE INFORMATION, COUN-
22 SELING, AND ASSISTANCE GRANTS.—

23 “(A) IN GENERAL.—There are hereby ap-
24 propriated to the Account from the Trust Fund
25 for each fiscal year beginning with fiscal year

2005, the amount described in subparagraph (B) for such fiscal year for the purpose of making grants under section 4360 of the Omnibus Budget Reconciliation Act of 1990.

“(B) AMOUNT DESCRIBED.—For purposes of subparagraph (A), the amount described in this subparagraph for a fiscal year is the amount equal to the product of—

- “(i) \$1; and
- “(ii) the total number of individuals receiving benefits under this title for the calendar year ending on December 31 of the preceding fiscal year.”.

(b) CONFORMING AMENDMENT.—Section 4360(g) of the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C. 1395b–4(g)) is amended to read as follows:

“(g) FUNDING.—The Secretary shall use amounts appropriated to the Consumer Ombudsman Account in accordance with section 1817(i) of the Social Security Act for a fiscal year for making grants under this section for that fiscal year.”.

SEC. 607. GAO STUDY REGARDING IMPACT OF ASSETS TEST FOR LOW-INCOME BENEFICIARIES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study to determine the extent to

1 which drug utilization and access to covered drugs for an
 2 individual described in subsection (b) differs from the drug
 3 utilization and access to covered drugs of an individual
 4 who qualifies for the transitional assistance prescription
 5 drug card program under section 1807A of the Social Se-
 6 curity Act (as added by section 111) or for the premiums
 7 and cost-sharing subsidies applicable to a qualified medi-
 8 care beneficiary, a specified low-income medicare bene-
 9 ficiary, or a qualifying individual under section 1860D-
 10 19 of the Social Security Act (as added by section 101).

11 (b) INDIVIDUAL DESCRIBED.—An individual is de-
 12 scribed in this subsection if the individual does not qualify
 13 for the transitional assistance prescription drug card pro-
 14 gram under section 1807A of the Social Security Act or
 15 for the premiums and cost-sharing subsidies applicable to
 16 a qualified medicare beneficiary, a specified low-income
 17 medicare beneficiary, or a qualifying individual under sec-
 18 tion 1860D–19 of the Social Security Act solely as a result
 19 of the application of an assets test to the individual.

20 (c) REPORT.—Not later than September 30, 2007,
 21 the Comptroller General shall submit a report to Congress
 22 on the study conducted under subsection (a) that includes
 23 such recommendations for legislation as the Comptroller
 24 General determines are appropriate.

25 (d) DEFINITIONS.—In this section:

(1) COVERED DRUGS.—The term “covered drugs” has the meaning given that term in section 1860D(a)(D) of the Social Security Act.

(2) QUALIFIED MEDICARE BENEFICIARY; SPECIFIED LOW-INCOME MEDICARE BENEFICIARY; QUALIFYING INDIVIDUAL.—The terms “qualified medicare beneficiary”, “specified low-income medicare beneficiary” and “qualifying individual” have the meaning given those terms under section 1860D–19 of the Social Security Act.

SEC. 608. HEALTH CARE INFRASTRUCTURE IMPROVEMENT.

At the end of the Social Security Act, add the following new title:

“TITLE XXII—HEALTH CARE INFRASTRUCTURE IMPROVEMENT

“SEC. 2201. DEFINITIONS.

“In this title, the following definitions apply:

“(1) ELIGIBLE PROJECT COSTS.—The term ‘eligible project costs’ means amounts substantially all of which are paid by, or for the account of, an obligor in connection with a project, including the cost of—

“(A) development phase activities, including planning, feasibility analysis, revenue fore-

1 casting, environmental study and review, per-
2 mitting, architectural engineering and design
3 work, and other preconstruction activities;

4 “(B) construction, reconstruction, rehabili-
5 tation, replacement, and acquisition of facilities
6 and real property (including land related to the
7 project and improvements to land), environ-
8 mental mitigation, construction contingencies,
9 and acquisition of equipment;

10 “(C) capitalized interest necessary to meet
11 market requirements, reasonably required re-
12 serve funds, capital issuance expenses, and
13 other carrying costs during construction;

14 “(D) major medical equipment determined
15 to be appropriate by the Secretary; and

16 “(E) refinancing projects or activities that
17 are otherwise eligible for financial assistance
18 under subparagraphs (A) through (D).

19 “(2) FEDERAL CREDIT INSTRUMENT.—The
20 term ‘Federal credit instrument’ means a secured
21 loan, loan guarantee, or line of credit authorized to
22 be made available under this title with respect to a
23 project.

24 “(3) INVESTMENT-GRADE RATING.—The term
25 ‘investment-grade rating’ means a rating category of

1 BBB minus, Baa3, or higher assigned by a rating
 2 agency to project obligations offered into the capital
 3 markets.

4 “(4) LENDER.—The term ‘lender’ means any
 5 non-Federal qualified institutional buyer (as defined
 6 in section 230.144A(a) of title 17, Code of Federal
 7 Regulations (or any successor regulation), known as
 8 Rule 144A(a) of the Securities and Exchange Com-
 9 mission and issued under the Securities Act of 1933
 10 (15 U.S.C. 77a et seq.)), including—

11 “(A) a qualified retirement plan (as de-
 12 fined in section 4974(c) of the Internal Revenue
 13 Code of 1986) that is a qualified institutional
 14 buyer; and

15 “(B) a governmental plan (as defined in
 16 section 414(d) of the Internal Revenue Code of
 17 1986) that is a qualified institutional buyer.

18 “(5) LINE OF CREDIT.—The term ‘line of cred-
 19 it’ means an agreement entered into by the Sec-
 20 retary with an obligor under section 2204 to provide
 21 a direct loan at a future date upon the occurrence
 22 of certain events.

23 “(6) LOAN GUARANTEE.—The term ‘loan guar-
 24 antee’ means any guarantee or other pledge by the
 25 Secretary to pay all or part of the principal of and

1 interest on a loan or other debt obligation issued by
2 an obligor and funded by a lender.

3 “(7) LOCAL SERVICER.—The term ‘local
4 servicer’ means a State or local government or any
5 agency of a State or local government that is re-
6 sponsible for servicing a Federal credit instrument
7 on behalf of the Secretary. *UNRECORDED*

8 “(8) OBLIGOR.—The term ‘obligor’ means a
9 party primarily liable for payment of the principal of
10 or interest on a Federal credit instrument, which
11 party may be a corporation, partnership, joint ven-
12 ture, trust, or governmental entity, agency, or in-
13 strumentality.

14 “(9) PROJECT.—The term ‘project’ means any
15 project that is designed to improve the health care
16 infrastructure, including the construction, renova-
17 tion, or other capital improvement of any hospital,
18 medical research facility, or other medical facility or
19 the purchase of any equipment to be used in a hos-
20 pital, research facility, or other medical research fa-
21 cility.

22 “(10) PROJECT OBLIGATION.—The term
23 ‘project obligation’ means any note, bond, debenture,
24 lease, installment sale agreement, or other debt obli-
25 gation issued or entered into by an obligor in con-

1 nection with the financing of a project, other than
2 a Federal credit instrument.

3 “(11) RATING AGENCY.—The term ‘rating
4 agency’ means a bond rating agency identified by
5 the Securities and Exchange Commission as a Na-
6 tionally Recognized Statistical Rating Organization.

7 “(12) SECURED LOAN.—The term ‘secured
8 loan’ means a direct loan or other debt obligation
9 issued by an obligor and funded by the Secretary in
10 connection with the financing of a project under sec-
11 tion 2203.

12 “(13) STATE.—The term ‘State’ has the mean-
13 ing given the term in section 101 of title 23, United
14 States Code.

15 “(14) SUBSIDY AMOUNT.—The term ‘subsidy
16 amount’ means the amount of budget authority suf-
17 ficient to cover the estimated long-term cost to the
18 Federal Government of a Federal credit instrument,
19 calculated on a net present value basis, excluding
20 administrative costs and any incidental effects on
21 governmental receipts or outlays in accordance with
22 the provisions of the Federal Credit Reform Act of
23 1990 (2 U.S.C. 661 et seq.).

1 “(15) SUBSTANTIAL COMPLETION.—The term
2 ‘substantial completion’ means the opening of a
3 project to patients or for research purposes.

4 **“SEC. 2202. DETERMINATION OF ELIGIBILITY AND PROJECT**
5 **SELECTION.**

6 “(a) ELIGIBILITY.—To be eligible to receive financial
7 assistance under this title, a project shall meet the fol-
8 lowing criteria:

9 “(1) APPLICATION.—A State, a local servicer
10 identified under section 2205(a), or the entity un-
11 dertaking a project shall submit a project application
12 to the Secretary.

13 “(2) ELIGIBLE PROJECT COSTS.—To be eligible
14 for assistance under this title, a project shall have
15 total eligible project costs that are reasonably antici-
16 pated to equal or exceed \$40,000,000.

17 “(3) SOURCES OF REPAYMENTS.—Project fi-
18 nancing shall be repayable, in whole or in part, from
19 reliable revenue sources as described in the applica-
20 tion submitted under paragraph (1).

21 “(4) PUBLIC SPONSORSHIP OF PRIVATE ENTI-
22 TIES.—In the case of a project that is undertaken
23 by an entity that is not a State or local government
24 or an agency or instrumentality of a State or local
25 government, the project that the entity is under-

1 taking shall be publicly sponsored or sponsored by
2 an entity that is described in section 501(c)(3) of
3 the Internal Revenue Code of 1986 and exempt from
4 tax under section 501(a) of such Code.

5 “(b) SELECTION AMONG ELIGIBLE PROJECTS.—

6 “(1) ESTABLISHMENT.—The Secretary shall es-
7 tablish criteria for selecting among projects that
8 meet the eligibility criteria specified in subsection
9 (a).

10 “(2) SELECTION CRITERIA.—

11 “(A) IN GENERAL.—The selection criteria
12 shall include the following:

13 “(i) The extent to which the project is
14 nationally or regionally significant, in
15 terms of expanding or improving the
16 health care infrastructure of the United
17 States or the region or in terms of the
18 medical benefit that the project will have.

19 “(ii) The creditworthiness of the
20 project, including a determination by the
21 Secretary that any financing for the
22 project has appropriate security features,
23 such as a rate covenant, credit enhance-
24 ment requirements, or debt services cov-
25 erages, to ensure repayment.

1 “(iii) The extent to which assistance
2 under this title would foster innovative
3 public-private partnerships and attract pri-
4 vate debt or equity investment.

5 “(iv) The likelihood that assistance
6 under this title would enable the project to
7 proceed at an earlier date than the project
8 would otherwise be able to proceed.

9 “(v) The extent to which the project
10 uses or results in new technologies.

11 “(vi) The amount of budget authority
12 required to fund the Federal credit instru-
13 ment made available under this title.

14 “(vii) The extent to which the project
15 helps maintain or protect the environment.

16 “(B) SPECIFIC REQUIREMENTS.—The se-
17 lection criteria shall require that a project ap-
18 plicant—

19 “(i) be engaged in research in the
20 causes, prevention, and treatment of can-
21 cer;

22 “(ii) be designated as a cancer center
23 for the National Cancer Institute or be
24 designated by the State as the official can-
25 cer institute of the State; and

“(iii) be located in a State that, on the date of enactment of this title, has a population of less than 3,000,000 individuals.

“(C) RATING LETTER.—For purposes of subparagraph (A)(ii), the Secretary shall require each project applicant to provide a rating letter from at least 1 rating agency indicating that the project’s senior obligations have the potential to achieve an investment-grade rating with or without credit enhancement.

“SEC. 2203. SECURED LOANS.

“(a) IN GENERAL.—

“(1) AGREEMENTS.—Subject to paragraphs (2) through (4), the Secretary may enter into agreements with 1 or more obligors to make secured loans, the proceeds of which shall be used—

“(A) to finance eligible project costs;

“(B) to refinance interim construction financing of eligible project costs; or

“(C) to refinance existing debt or prior project obligations;
of any project selected under section 2202.

“(2) LIMITATION ON REFINANCING OF INTERIM CONSTRUCTION FINANCING.—A loan under para-

1 graph (1) shall not refinance interim construction fi-
2 nancing under paragraph (1)(B) later than 1 year
3 after the date of substantial completion of the
4 project.

5 “(3) RISK ASSESSMENT.—Before entering into
6 an agreement for a secured loan under this sub-
7 section, the Secretary, in consultation with each rat-
8 ing agency providing a rating letter under section
9 2202(b)(2)(B), shall determine an appropriate cap-
10 ital reserve subsidy amount for each secured loan,
11 taking into account such letter.

12 “(4) INVESTMENT-GRADE RATING REQUIRE-
13 MENT.—The funding of a secured loan under this
14 section shall be contingent on the project’s senior
15 obligations receiving an investment-grade rating, ex-
16 cept that—

17 “(A) the Secretary may fund an amount of
18 the secured loan not to exceed the capital re-
19 serve subsidy amount determined under para-
20 graph (3) prior to the obligations receiving an
21 investment-grade rating; and

22 “(B) the Secretary may fund the remain-
23 ing portion of the secured loan only after the
24 obligations have received an investment-grade
25 rating by at least 1 rating agency.

1 “(b) TERMS AND LIMITATIONS.—

2 “(1) IN GENERAL.—A secured loan under this
3 section with respect to a project shall be on such
4 terms and conditions and contain such covenants,
5 representations, warranties, and requirements (in-
6 cluding requirements for audits) as the Secretary de-
7 termines appropriate.

8 “(2) MAXIMUM AMOUNT.—The amount of the
9 secured loan shall not exceed 100 percent of the rea-
10 sonably anticipated eligible project costs.

11 “(3) PAYMENT.—The secured loan—

12 “(A) shall—

13 “(i) be payable, in whole or in part,
14 from reliable revenue sources; and

15 “(ii) include a rate covenant, coverage
16 requirement, or similar security feature
17 supporting the project obligations; and

18 “(B) may have a lien on revenues de-
19 scribed in subparagraph (A) subject to any lien
20 securing project obligations.

21 “(4) INTEREST RATE.—The interest rate on the
22 secured loan shall be not less than the yield on mar-
23 ketable United States Treasury securities of a simi-
24 lar maturity to the maturity of the secured loan on
25 the date of execution of the loan agreement.

1 “(5) MATURITY DATE.—The final maturity
2 date of the secured loan shall be not later than 30
3 years after the date of substantial completion of the
4 project.

5 “(6) NONSUBORDINATION.—The secured loan
6 shall not be subordinated to the claims of any holder
7 of project obligations in the event of bankruptcy, in-
8 solveny, or liquidation of the obligor.

9 “(7) FEES.—The Secretary may establish fees
10 at a level sufficient to cover all or a portion of the
11 costs to the Federal Government of making a se-
12 cured loan under this section.

13 “(c) REPAYMENT.—

14 “(1) SCHEDULE.—The Secretary shall establish
15 a repayment schedule for each secured loan under
16 this section based on the projected cash flow from
17 project revenues and other repayment sources.

18 “(2) COMMENCEMENT.—Scheduled loan repay-
19 ments of principal or interest on a secured loan
20 under this section shall commence not later than 5
21 years after the date of substantial completion of the
22 project.

23 “(3) SOURCES OF REPAYMENT FUNDS.—The
24 sources of funds for scheduled loan repayments

under this section shall include any revenue generated by the project.

“(4) DEFERRED PAYMENTS.—

“(A) AUTHORIZATION.—If, at any time during the 10 years after the date of substantial completion of the project, the project is unable to generate sufficient revenues to pay the scheduled loan repayments of principal and interest on the secured loan, the Secretary may, subject to subparagraph (C), allow the obligor to add unpaid principal and interest to the outstanding balance of the secured loan.

“(B) INTEREST.—Any payment deferred under subparagraph (A) shall—

“(i) continue to accrue interest in accordance with subsection (b)(4) until fully repaid; and

“(ii) be scheduled to be amortized over the remaining term of the loan beginning not later than 10 years after the date of substantial completion of the project in accordance with paragraph (1).

“(C) CRITERIA.—

“(i) IN GENERAL.—Any payment deferral under subparagraph (A) shall be

1 contingent on the project meeting criteria
2 established by the Secretary.

3 “(ii) REPAYMENT STANDARDS.—The
4 criteria established under clause (i) shall
5 include standards for reasonable assurance
6 of repayment.

7 “(5) PREPAYMENT.—

8 “(A) USE OF EXCESS REVENUES.—Any
9 excess revenues that remain after satisfying
10 scheduled debt service requirements on the
11 project obligations and secured loan and all de-
12 posit requirements under the terms of any trust
13 agreement, bond resolution, reimbursement
14 agreement, credit agreement, loan agreement,
15 or similar agreement securing project obliga-
16 tions may be applied annually to prepay the se-
17 cured loan without penalty.

18 “(B) USE OF PROCEEDS OF REFI-
19 NANCING.—The secured loan may be prepaid at
20 any time without penalty, regardless of whether
21 such repayment is from the proceeds of refi-
22 nancing from non-Federal funding sources.

23 “(6) FORGIVENESS OF INDEBTEDNESS.—The
24 Secretary may forgive a loan secured under this title
25 under terms and conditions that are analogous to

1 the loan forgiveness provision for student loans
 2 under part D of title IV of the Higher Education
 3 Act of 1965 (20 U.S.C. 1087a et seq.), except that
 4 the Secretary shall condition such forgiveness on the
 5 establishment by the project of—

6 “(A) an outreach program for cancer pre-
 7 vention, early diagnosis, and treatment that
 8 provides services to a substantial majority of
 9 the residents of a State or region, including
 10 residents of rural areas;

11 “(B) an outreach program for cancer pre-
 12 vention, early diagnosis, and treatment that
 13 provides services to multiple Indian tribes; and

14 “(C)(i) unique research resources (such as
 15 population databases); or

16 “(ii) an affiliation with an entity that has
 17 unique research resources.

18 “(d) SALE OF SECURED LOANS.—

19 “(1) IN GENERAL.—Subject to paragraph (2),
 20 as soon as practicable after substantial completion of
 21 a project and after notifying the obligor, the Sec-
 22 retary may sell to another entity or reoffer into the
 23 capital markets a secured loan for the project if the
 24 Secretary determines that the sale or reoffering can
 25 be made on favorable terms.

1 “(2) CONSENT OF OBLIGOR.—In making a sale
2 or reoffering under paragraph (1), the Secretary
3 may not change the original terms and conditions of
4 the secured loan without the written consent of the
5 obligor.

6 “(e) LOAN GUARANTEES.—

7 “(1) IN GENERAL.—The Secretary may provide
8 a loan guarantee to a lender in lieu of making a se-
9 cured loan if the Secretary determines that the
10 budgetary cost of the loan guarantee is substantially
11 the same as that of a secured loan.

12 “(2) TERMS.—The terms of a guaranteed loan
13 shall be consistent with the terms set forth in this
14 section for a secured loan, except that the rate on
15 the guaranteed loan and any prepayment features
16 shall be negotiated between the obligor and the lend-
17 er, with the consent of the Secretary.

18 **“SEC. 2204. LINES OF CREDIT.**

19 “(a) IN GENERAL.—

20 “(1) AGREEMENTS.—Subject to paragraphs (2)
21 through (4), the Secretary may enter into agree-
22 ments to make available lines of credit to 1 or more
23 obligors in the form of direct loans to be made by
24 the Secretary at future dates on the occurrence of

certain events for any project selected under section 2202.

“(2) USE OF PROCEEDS.—The proceeds of a line of credit made available under this section shall be available to pay debt service on project obligations issued to finance eligible project costs, extraordinary repair and replacement costs, operation and maintenance expenses, and costs associated with unexpected Federal or State environmental restrictions.

“(3) RISK ASSESSMENT.—Before entering into an agreement for a secured loan under this subsection, the Secretary, in consultation with each rating agency providing a rating letter under section 2202(b)(2)(B), shall determine an appropriate subsidy amount for each secured loan, taking into account such letter.

“(4) INVESTMENT-GRADE RATING REQUIREMENT.—The funding of a line of credit under this section shall be contingent on the project’s senior obligations receiving an investment-grade rating from at least 1 rating agency.

“(b) TERMS AND LIMITATIONS.—

“(1) IN GENERAL.—A line of credit under this section with respect to a project shall be on such terms and conditions and contain such covenants,

1 representations, warranties, and requirements (in-
2 cluding requirements for audits) as the Secretary de-
3 termines appropriate.

4 “(2) MAXIMUM AMOUNTS.—

5 “(A) TOTAL AMOUNT.—The total amount
6 of the line of credit shall not exceed 33 percent
7 of the reasonably anticipated eligible project
8 costs.

9 “(B) 1-YEAR DRAWS.—The amount drawn
10 in any 1 year shall not exceed 20 percent of the
11 total amount of the line of credit.

12 “(3) DRAWS.—Any draw on the line of credit
13 shall represent a direct loan and shall be made only
14 if net revenues from the project (including capital-
15 ized interest, any debt service reserve fund, and any
16 other available reserve) are insufficient to pay the
17 costs specified in subsection (a)(2).

18 “(4) INTEREST RATE.—The interest rate on a
19 direct loan resulting from a draw on the line of cred-
20 it shall be not less than the yield on 30-year market-
21 able United States Treasury securities as of the date
22 on which the line of credit is obligated.

23 “(5) SECURITY.—The line of credit—

24 “(A) shall—

“(i) be payable, in whole or in part,
from reliable revenue sources; and

“(ii) include a rate covenant, coverage
requirement, or similar security feature
supporting the project obligations; and

“(B) may have a lien on revenues de-
scribed in subparagraph (A) subject to any lien
securing project obligations.”

“(6) PERIOD OF AVAILABILITY.—The line of
credit shall be available during the period beginning
on the date of substantial completion of the project
and ending not later than 10 years after that date.

“(7) RIGHTS OF THIRD-PARTY CREDITORS.—

“(A) AGAINST FEDERAL GOVERNMENT.—A
third-party creditor of the obligor shall not have
any right against the Federal Government with
respect to any draw on the line of credit.

“(B) ASSIGNMENT.—An obligor may as-
sign the line of credit to 1 or more lenders or
to a trustee on the lenders’ behalf.

“(8) NONSUBORDINATION.—A direct loan
under this section shall not be subordinated to the
claims of any holder of project obligations in the
event of bankruptcy, insolvency, or liquidation of the
obligor.

1 “(9) FEES.—The Secretary may establish fees
2 at a level sufficient to cover all or a portion of the
3 costs to the Federal Government of providing a line
4 of credit under this section.

5 “(10) RELATIONSHIP TO OTHER CREDIT IN-
6 STRUMENTS.—A project that receives a line of credit
7 under this section also shall not receive a secured
8 loan or loan guarantee under section 2203 of an
9 amount that, combined with the amount of the line
10 of credit, exceeds 100 percent of eligible project
11 costs.

12 “(c) REPAYMENT.—

13 “(1) TERMS AND CONDITIONS.—The Secretary
14 shall establish repayment terms and conditions for
15 each direct loan under this section based on the pro-
16 jected cash flow from project revenues and other re-
17 payment sources.

18 “(2) TIMING.—All scheduled repayments of
19 principal or interest on a direct loan under this sec-
20 tion shall commence not later than 5 years after the
21 end of the period of availability specified in sub-
22 section (b)(6) and be fully repaid, with interest, by
23 the date that is 25 years after the end of the period
24 of availability specified in subsection (b)(6).

1 “(3) SOURCES OF REPAYMENT FUNDS.—The
2 sources of funds for scheduled loan repayments
3 under this section shall include reliable revenue
4 sources.

5 **“SEC. 2205. PROJECT SERVICING.**

6 “(a) REQUIREMENT.—The State in which a project
7 that receives financial assistance under this title is located
8 may identify a local servicer to assist the Secretary in
9 servicing the Federal credit instrument made available
10 under this title.

11 “(b) AGENCY; FEES.—If a State identifies a local
12 servicer under subsection (a), the local servicer—

13 “(1) shall act as the agent for the Secretary;
14 and

15 “(2) may receive a servicing fee, subject to ap-
16 proval by the Secretary.

17 “(c) LIABILITY.—A local servicer identified under
18 subsection (a) shall not be liable for the obligations of the
19 obligor to the Secretary or any lender.

20 “(d) ASSISTANCE FROM EXPERT FIRMS.—The Sec-
21 retary may retain the services of expert firms in the field
22 of project finance to assist in the underwriting and serv-
23 icing of Federal credit instruments.

1 **"SEC. 2206. STATE AND LOCAL PERMITS.**

2 "The provision of financial assistance under this title
3 with respect to a project shall not—

4 "(1) relieve any recipient of the assistance of
5 any obligation to obtain any required State or local
6 permit or approval with respect to the project;

7 "(2) limit the right of any unit of State or local
8 government to approve or regulate any rate of re-
9 turn on private equity invested in the project; or

10 "(3) otherwise supersede any State or local law
11 (including any regulation) applicable to the construc-
12 tion or operation of the project.

13 **"SEC. 2207. REGULATIONS.**

14 "The Secretary may issue such regulations as the
15 Secretary determines appropriate to carry out this title.

16 **"SEC. 2208. FUNDING.**

17 "(a) FUNDING.—

18 "(1) IN GENERAL.—There are authorized to be
19 appropriated to carry out this title, \$49,000,000 to
20 remain available during the period beginning on July
21 1, 2004 and ending on September 30, 2008.

22 "(2) ADMINISTRATIVE COSTS.—From funds
23 made available under paragraph (1), the Secretary
24 may use, for the administration of this title, not
25 more than \$2,000,000 for each of fiscal years 2004
26 through 2008.

1 “(b) CONTRACT AUTHORITY.—Notwithstanding any
 2 other provision of law, approval by the Secretary of a Fed-
 3 eral credit instrument that uses funds made available
 4 under this title shall be deemed to be acceptance by the
 5 United States of a contractual obligation to fund the Fed-
 6 eral credit instrument.

7 “(c) AVAILABILITY.—Amounts appropriated under
 8 this section shall be available for obligation on July 1,
 9 2004.

10 **“SEC. 2209. REPORT TO CONGRESS.**

11 “Not later than 4 years after the date of enactment
 12 of this title, the Secretary shall submit to Congress a re-
 13 port summarizing the financial performance of the
 14 projects that are receiving, or have received, assistance
 15 under this title, including a recommendation as to whether
 16 the objectives of this title are best served—

17 “(1) by continuing the program under the au-
 18 thority of the Secretary;

19 “(2) by establishing a Government corporation
 20 or Government-sponsored enterprise to administer
 21 the program; or

22 “(3) by phasing out the program and relying on
 23 the capital markets to fund the types of infrastruc-
 24 ture investments assisted by this title without Fed-
 25 eral participation.”.

1 **SEC. 609. CAPITAL INFRASTRUCTURE REVOLVING LOAN**
 2 **PROGRAM.**

3 (a) IN GENERAL.—Part A of title XVI of the Public
 4 Health Service Act (42 U.S.C. 300q et seq.) is amended
 5 by adding at the end the following new section:

6 “CAPITAL INFRASTRUCTURE REVOLVING LOAN PROGRAM
 7 “SEC. 1603. (a) AUTHORITY TO MAKE AND GUAR-
 8 ANTEE LOANS.—

9 “(1) AUTHORITY TO MAKE LOANS.—The Sec-
 10 retary may make loans from the fund established
 11 under section 1602(d) to any rural entity for
 12 projects for capital improvements, including—

13 “(A) the acquisition of land necessary for
 14 the capital improvements;

15 “(B) the renovation or modernization of
 16 any building;

17 “(C) the acquisition or repair of fixed or
 18 major movable equipment; and

19 “(D) such other project expenses as the
 20 Secretary determines appropriate.

21 “(2) AUTHORITY TO GUARANTEE LOANS.—

22 “(A) IN GENERAL.—The Secretary may
 23 guarantee the payment of principal and interest
 24 for loans made to rural entities for projects for
 25 any capital improvement described in paragraph
 26 (1) to any non-Federal lender.

“(B) INTEREST SUBSIDIES.—In the case of a guarantee of any loan made to a rural entity under subparagraph (A), the Secretary may pay to the holder of such loan, for and on behalf of the project for which the loan was made, amounts sufficient to reduce (by not more than 3 percent) the net effective interest rate otherwise payable on such loan.

“(b) AMOUNT OF LOAN.—The principal amount of a loan directly made or guaranteed under subsection (a) for a project for capital improvement may not exceed \$5,000,000.

“(c) FUNDING LIMITATIONS.—

“(1) GOVERNMENT CREDIT SUBSIDY EXPOSURE.—The total of the Government credit subsidy exposure under the Credit Reform Act of 1990 scoring protocol with respect to the loans outstanding at any time with respect to which guarantees have been issued, or which have been directly made, under subsection (a) may not exceed \$50,000,000 per year.

“(2) TOTAL AMOUNTS.—Subject to paragraph (1), the total of the principal amount of all loans directly made or guaranteed under subsection (a) may not exceed \$250,000,000 per year.

1 “(d) CAPITAL ASSESSMENT AND PLANNING
2 GRANTS.—

3 “(1) NONREPAYABLE GRANTS.—Subject to
4 paragraph (2), the Secretary may make a grant to
5 a rural entity, in an amount not to exceed \$50,000,
6 for purposes of capital assessment and business
7 planning.

8 “(2) LIMITATION.—The cumulative total of
9 grants awarded under this subsection may not ex-
10 ceed \$2,500,000 per year.

11 “(e) TERMINATION OF AUTHORITY.—The Secretary
12 may not directly make or guarantee any loan under sub-
13 section (a) or make a grant under subsection (d) after
14 September 30, 2008.”.

15 (b) RURAL ENTITY DEFINED.—Section 1624 of the
16 Public Health Service Act (42 U.S.C. 300s–3) is amended
17 by adding at the end the following new paragraph:

18 “(14)(A) The term ‘rural entity’ includes—

19 “(i) a rural health clinic, as defined in sec-
20 tion 1861(aa)(2) of the Social Security Act;

21 “(ii) any medical facility with at least 1
22 bed, but with less than 50 beds, that is located
23 in—

24 “(I) a county that is not part of a
25 metropolitan statistical area; or

“(II) a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725));

“(iii) a hospital that is classified as a rural, regional, or national referral center under section 1886(d)(5)(C) of the Social Security Act; and

“(iv) a hospital that is a sole community hospital (as defined in section 1886(d)(5)(D)(iii) of the Social Security Act).

“(B) For purposes of subparagraph (A), the fact that a clinic, facility, or hospital has been geographically reclassified under the medicare program under title XVIII of the Social Security Act shall not preclude a hospital from being considered a rural entity under clause (i) or (ii) of subparagraph (A).”.

(c) CONFORMING AMENDMENTS.—Section 1602 of the Public Health Service Act (42 U.S.C. 300q-2) is amended—

(1) in subsection (b)(2)(D), by inserting “or 1603(a)(2)(B)” after “1601(a)(2)(B)”; and

(2) in subsection (d)—

1 (A) in paragraph (1)(C), by striking “sec-
 2 tion 1601(a)(2)(B)” and inserting “sections
 3 1601(a)(2)(B) and 1603(a)(2)(B)”; and
 4 (B) in paragraph (2)(A), by inserting “or
 5 1603(a)(2)(B)” after “1601(a)(2)(B)”.

6 **SEC. 610. FEDERAL REIMBURSEMENT OF EMERGENCY**
 7 **HEALTH SERVICES FURNISHED TO UNDOCU-**
 8 **MENTED ALIENS.**

9 (a) TOTAL AMOUNT AVAILABLE FOR ALLOTMENT.—
 10 There is appropriated, out of any funds in the Treasury
 11 not otherwise appropriated, \$250,000,000 for each of fis-
 12 cal years 2005 through 2008, for the purpose of making
 13 allotments under this section to States described in para-
 14 graph (1) or (2) of subsection (b). Funds appropriated
 15 under the preceding sentence shall remain available until
 16 expended.

17 (b) STATE ALLOTMENTS.—

18 (1) BASED ON PERCENTAGE OF UNDOCU-
 19 MENTED ALIENS.—

20 (A) IN GENERAL.—Out of the amount ap-
 21 propriated under subsection (a) for a fiscal
 22 year, the Secretary shall use \$167,000,000 of
 23 such amount to make allotments for such fiscal
 24 year in accordance with subparagraph (B).

(B) FORMULA.—The amount of the allotment for each State for a fiscal year shall be equal to the product of—

(i) the total amount available for allotments under this paragraph for the fiscal year; and

(ii) the percentage of undocumented aliens residing in the State with respect to the total number of such aliens residing in all States, as determined by the Statistics Division of the Immigration and Naturalization Service, as of January 2003, based on the 2000 decennial census.

(2) BASED ON NUMBER OF UNDOCUMENTED ALIEN APPREHENSION STATES.—

(A) IN GENERAL.—Out of the amount appropriated under subsection (a) for a fiscal year, the Secretary shall use \$83,000,000 of such amount to make allotments for such fiscal year for each of the 6 States with the highest number of undocumented alien apprehensions for such fiscal year.

(B) DETERMINATION OF ALLOTMENTS.—The amount of the allotment for each State described in subparagraph (A) for a fiscal year

1 shall bear the same ratio to the total amount
 2 available for allotments under this paragraph
 3 for the fiscal year as the ratio of the number
 4 of undocumented alien apprehensions in the
 5 State in that fiscal year bears to the total of
 6 such numbers for all such States for such fiscal
 7 year.

8 (C) DATA.—For purposes of this para-
 9 graph, the highest number of undocumented
 10 alien apprehensions for a fiscal year shall be
 11 based on the 4 most recent quarterly apprehen-
 12 sion rates for undocumented aliens in such
 13 States, as reported by the Immigration and
 14 Naturalization Service.

15 (3) RULE OF CONSTRUCTION.—Nothing in this
 16 section shall be construed as prohibiting a State that
 17 is described in both of paragraphs (1) and (2) from
 18 receiving an allotment under both paragraphs for a
 19 fiscal year.

20 (c) USE OF FUNDS.—

21 (1) AUTHORITY TO MAKE PAYMENTS.—From
 22 the allotments made for a State under subsection (b)
 23 for a fiscal year, the Secretary shall pay directly to
 24 local governments, hospitals, or other providers lo-
 25 cated in the State (including providers of services re-

ceived through an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization) that provide uncompensated emergency health services furnished to undocumented aliens during that fiscal year, and to the State, such amounts (subject to the total amount available from such allotments) as the local governments, hospitals, providers, or State demonstrate were incurred for the provision of such services during that fiscal year.

(2) LIMITATION ON STATE USE OF FUNDS.—

Funds paid to a State from allotments made under subsection (b) for a fiscal year may only be used for making payments to local governments, hospitals, or other providers for costs incurred in providing emergency health services to undocumented aliens or for State costs incurred with respect to the provision of emergency health services to such aliens.

(3) INCLUSION OF COSTS INCURRED WITH RESPECT TO CERTAIN ALIENS.—Uncompensated emergency health services furnished to aliens who have been allowed to enter the United States for the sole purpose of receiving emergency health services may be included in the determination of costs incurred by

1 a State, local government, hospital, or other provider
2 with respect to the provision of such services.

3 (d) APPLICATIONS; ADVANCE PAYMENTS.—

4 (1) DEADLINE FOR ESTABLISHMENT OF APPLI-
5 CATION PROCESS.—24 (A) IN GENERAL.—Not
6 later than September 1, 2004, the Secretary shall
7 establish a process under which States, local govern-
8 ments, hospitals, or other providers located in the
9 State may apply for payments from allotments made
10 under subsection (b) for a fiscal year for uncompen-
11 sated emergency health services furnished to un-
12 documented aliens during that fiscal year.

13 (B) INCLUSION OF MEASURES TO COMBAT
14 FRAUD.—The Secretary shall include in the
15 process established under subparagraph (A)
16 measures to ensure that fraudulent payments
17 are not made from the allotments determined
18 under subsection (b).

19 (2) ADVANCE PAYMENT; RETROSPECTIVE AD-
20 JUSTMENT.—The process established under para-
21 graph (1) shall allow for making payments under
22 this section for each quarter of a fiscal year on the
23 basis of advance estimates of expenditures submitted
24 by applicants for such payments and such other in-
25 vestigation as the Secretary may find necessary, and

1 for making reductions or increases in the payments
2 as necessary to adjust for any overpayment or un-
3 derpayment for prior quarters of such fiscal year.

4 (e) DEFINITIONS.—In this section:

5 (1) HOSPITAL.—The term “hospital” has the
6 meaning given such term in section 1861(e) of the
7 Social Security Act (42 U.S.C. 1395x(e)).

8 (2) INDIAN TRIBE; TRIBAL ORGANIZATION.—
9 The terms “Indian tribe” and “tribal organization”
10 have the meanings given such terms in section 4 of
11 the Indian Health Care Improvement Act (25 U.S.C.
12 1603).

13 (3) PROVIDER.—The term “provider” includes
14 a physician, any other health care professional li-
15 censed under State law, and any other entity that
16 furnishes emergency health services, including ambu-
17 lance services.

18 (4) SECRETARY.—The term “Secretary” means
19 the Secretary of Health and Human Services.

20 (5) STATE.—The term “State” means the 50
21 States and the District of Columbia.

1 **SEC. 611. INCREASE IN APPROPRIATION TO THE HEALTH**
2 **CARE FRAUD AND ABUSE CONTROL AC-**
3 **COUNT.**

4 Section 1817(k)(3)(A) (42 U.S.C. 1395i(k)(3)(A)) is
5 amended—

6 (1) in clause (i)—

7 (A) in subclause (II), by striking “and” at
8 the end; and

9 (B) by striking subclause (III), and insert-
10 ing the following new subclauses:

11 “(III) for fiscal year 2004, the
12 limit for fiscal year 2003 increased by
13 \$10,000,000;

14 “(IV) for fiscal year 2005, the
15 limit for fiscal year 2003 increased by
16 \$15,000,000;

17 “(V) for fiscal year 2006, the
18 limit for fiscal year 2003 increased by
19 \$25,000,000; and

20 “(VI) for each fiscal year after
21 fiscal year 2006, the limit for fiscal
22 year 2003.”; and

23 (2) in clause (ii)—

24 (A) in subclause (VI), by striking “and” at
25 the end;

26 (B) in subclause (VII)—

(i) by striking “each fiscal year after fiscal year 2002” and inserting “fiscal year 2003”; and

(ii) by striking the period and inserting a semicolon; and

(3) by adding at the end the following:

“(VIII) for fiscal year 2004, \$170,000,000;

“(IX) for fiscal year 2005, \$175,000,000;

“(X) for fiscal year 2006, \$185,000,000; and

“(XI) for each fiscal year after fiscal year 2006, not less than \$150,000,000 and not more than \$160,000,000.”.

SEC. 612. INCREASE IN CIVIL PENALTIES UNDER THE FALSE CLAIMS ACT.

(a) IN GENERAL.—Section 3729(a) of title 31, United States Code, is amended—

(1) by striking “\$5,000” and inserting “\$7,500”; and

(2) by striking “\$10,000” and inserting “\$15,000”.

1 (b) EFFECTIVE DATE.—The amendments made by
 2 subsection (a) shall apply to violations occurring on or
 3 after January 1, 2004.

4 **SEC. 613. INCREASE IN CIVIL MONETARY PENALTIES**
 5 **UNDER THE SOCIAL SECURITY ACT.**

6 (a) IN GENERAL.—Section 1128A(a) (42 U.S.C.
 7 1320a-7a(a)), in the matter following paragraph (7), is
 8 amended—

9 (1) by striking “\$10,000” each place it appears
 10 and inserting “\$12,500”;

11 (2) by striking “\$15,000” and inserting
 12 “\$18,750”; and

13 (3) striking “\$50,000” and inserting
 14 “\$62,500”.

15 (b) EFFECTIVE DATE.—The amendments made by
 16 subsection (a) shall apply to violations occurring on or
 17 after January 1, 2004.

18 **SEC. 614. EXTENSION OF CUSTOMS USER FEES.**

19 Section 13031(j)(3) of the Consolidated Omnibus
 20 Budget Reconciliation Act of 1985 (19 U.S.C. 58c(j)(3))
 21 is amended by striking “September 30, 2003” and insert-
 22 ing “September 30, 2013”.

1 **SEC. 615. REIMBURSEMENT FOR FEDERALLY QUALIFIED**
 2 **HEALTH CENTERS PARTICIPATING IN MEDI-**
 3 **CARE MANAGED CARE.**

4 (a) REIMBURSEMENT.—

5 (1) IN GENERAL.—Section 1833(a)(3) (42
 6 U.S.C. 1395l(a)(3)) is amended to read as follows:

7 “(3) in the case of services described in section
 8 1832(a)(2)(D)—

9 “(A) except as provided in subparagraph
 10 (B), the costs which are reasonable and related
 11 to the cost of furnishing such services or which
 12 are based on such other tests of reasonableness
 13 as the Secretary may prescribe in regulations,
 14 including those authorized under section
 15 1861(v)(1)(A), less the amount a provider may
 16 charge as described in clause (ii) of section
 17 1866(a)(2)(A), but in no case may the payment
 18 for such services (other than for items and serv-
 19 ices described in section 1861(s)(10)(A)) exceed
 20 80 percent of such costs; or

21 “(B) with respect to the services described
 22 in clause (ii) of section 1832(a)(2)(D) that are
 23 furnished to an individual enrolled with a
 24 Medicare Advantage plan under part C pursuant
 25 to a written agreement described in section
 26 1853(j), the amount by which—

1 “(i) the amount of payment that
 2 would have otherwise been provided under
 3 subparagraph (A) (calculated as if ‘100
 4 percent’ were substituted for ‘80 percent’
 5 in such subparagraph) for such services if
 6 the individual had not been so enrolled; ex-
 7 ceeds
 8 “(ii) the amount of the payments re-
 9 ceived under such written agreement for
 10 such services (not including any financial
 11 incentives provided for in such agreement
 12 such as risk pool payments, bonuses, or
 13 withholds),
 14 less the amount the Federally qualified health
 15 center may charge as described in section
 16 1857(e)(3)(C);”.

17 (b) CONTINUATION OF MEDICAREADVANTAGE
 18 MONTHLY PAYMENTS.—

19 (1) IN GENERAL.—Section 1853 (42 U.S.C.
 20 1395w-23), as amended by this Act, is amended by
 21 adding at the end the following new subsection:

22 “(j) PAYMENT RULE FOR FEDERALLY QUALIFIED
 23 HEALTH CENTER SERVICES.—If an individual who is en-
 24 rolled with a MedicareAdvantage plan under this part re-
 25 ceives a service from a Federally qualified health center

1 that has a written agreement with such plan for providing
 2 such a service (including any agreement required under
 3 section 1857(e)(3))—

4 “(1) the Secretary shall pay the amount deter-
 5 mined under section 1833(a)(3)(B) directly to the
 6 Federally qualified health center not less frequently
 7 than quarterly; and

8 “(2) the Secretary shall not reduce the amount
 9 of the monthly payments to the MedicareAdvantage
 10 plan made under section 1853(a) as a result of the
 11 application of paragraph (1).”.

12 (2) CONFORMING AMENDMENTS.—

13 (A) Paragraphs (1) and (2) of section
 14 1851(i) (42 U.S.C. 1395w-21(i)(1)), as amend-
 15 ed by this Act, are each amended by inserting
 16 “1853(j),” after “1853(i),”.

17 (B) Section 1853(c)(5) is amended by
 18 striking “subsections (a)(3)(C)(iii) and (i)” and
 19 inserting “subsections (a)(3)(C)(iii), (i), and
 20 (j)(1)”.

21 (c) ADDITIONAL MEDICAREADVANTAGE CONTRACT
 22 REQUIREMENTS.—Section 1857(e) (42 U.S.C. 1395w-
 23 27(e)) is amended by adding at the end the following new
 24 paragraph:

1 “(3) AGREEMENTS WITH FEDERALLY QUALI-
2 FIED HEALTH CENTERS.—

3 “(A) PAYMENT LEVELS AND AMOUNTS.—A
4 contract under this part shall require the
5 MedicareAdvantage plan to provide, in any con-
6 tract between the plan and a Federally qualified
7 health center, for a level and amount of pay-
8 ment to the Federally qualified health center
9 for services provided by such health center that
10 is not less than the level and amount of pay-
11 ment that the plan would make for such serv-
12 ices if the services had been furnished by a pro-
13 vider of services that was not a Federally quali-
14 fied health center.

15 “(B) COST-SHARING.—Under the written
16 agreement described in subparagraph (A), a
17 Federally qualified health center must accept
18 the MedicareAdvantage contract price plus the
19 Federal payment provided for in section
20 1833(a)(3)(B) as payment in full for services
21 covered by the contract, except that such a
22 health center may collect any amount of cost-
23 sharing permitted under the contract under this
24 part, so long as the amounts of any deductible,

coinsurance, or copayment comply with the requirements under section 1854(e).”.

(d) **SAFE HARBOR FROM ANTICKICKBACK PROHIBITION.**—Section 1128B(b)(3) (42 U.S.C. 1320a–7b(b)(3))

is amended—

(1) in subparagraph (E), by striking “and” after the semicolon at the end;

(2) in subparagraph (F), by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following new subparagraph:

“(G) any remuneration between a Federally qualified health center (or an entity controlled by such a health center) and a Medicare Advantage plan pursuant to the written agreement described in section 1853(j).”.

(e) **EFFECTIVE DATE.**—The amendments made by this section shall apply to services provided on or after January 1, 2006, and contract years beginning on or after such date.

SEC. 616. PROVISION OF INFORMATION ON ADVANCE DIRECTIVES.

Section 1804(c) of the Social Security Act (42 U.S.C. 1395b-2(c)) is amended—

1 (1) by redesignating paragraphs (1) through
 2 (4) as subparagraphs (A) through (D), respectively;
 3 (2) in the matter preceding subparagraph (A),
 4 as so redesignated, by striking "The notice" and in-
 5 serting "(1) The notice"; and

6 (3) by adding at the end the following:

7 "(2)(A) The Secretary shall annually provide each
 8 medicare beneficiary with information concerning advance
 9 directives. Such information shall be provided by the Sec-
 10 retary as part of the Medicare and You handbook that
 11 is provided to each such beneficiary. Such handbook shall
 12 include a separate section on advanced directives and spe-
 13 cific details on living wills and the durable power of attor-
 14 ney for health care. The Secretary shall ensure that the
 15 introductory letter that accompanies such handbook con-
 16 tain a statement concerning the inclusion of such informa-
 17 tion.

18 "(B) In this section:

19 "(i) The term 'advance directive' has the mean-
 20 ing given such term in section 1866(f)(3).

21 "(ii) The term 'medicare beneficiary' means an
 22 individual who is entitled to, or enrolled for, benefits
 23 under part A or enrolled under part B, of this
 24 title."

1 **SEC. 617. SENSE OF THE SENATE REGARDING IMPLEMEN-**
 2 **TATION OF THE PRESCRIPTION DRUG AND**
 3 **MEDICARE IMPROVEMENT ACT OF 2003.**

4 (a) IN GENERAL.—It is the sense of the Senate that
 5 the Committee on Finance of the Senate should hold not
 6 less than 4 hearings to monitor implementation of the Pre-
 7 scription Drug and Medicare Improvement Act of 2003
 8 (hereinafter in this section referred to as the “Act”) dur-
 9 ing which the Secretary or his designee should testify be-
 10 fore the Committee.

11 (b) INITIAL HEARING.—It is the sense of the Senate
 12 that the first hearing described in subsection (a) should
 13 be held not later than 60 days after the date of the enact-
 14 ment the Act. At the hearing, the Secretary or his des-
 15 ignee should submit written testimony and testify before
 16 the Committee on Finance of the Senate on the following
 17 issues:

18 (1) The progress toward implementation of the
 19 prescription drug discount card under section 111 of
 20 the Act.

21 (2) Development of the blueprint that will di-
 22 rect the implementation of the provisions of the Act,
 23 including the implementation of title I (Medicare
 24 Prescription Drug Benefit), title II
 25 (Medicare Advantage), and title III (Center for Medi-
 26 care Choices) of the Act.

1 (3) Any problems that will impede the timely
2 implementation of the Act.

3 (4) The overall progress toward implementation
4 of the Act.

5 (c) SUBSEQUENT HEARINGS.—It is the sense of the
6 Senate that the additional hearings described in sub-
7 section (a) should be held in each of May 2004, October
8 2004, and May 2005. At each hearing, the Secretary or
9 his designee should submit written testimony and testify
10 before the Committee on Finance of the Senate on the
11 following issues:

12 (1) Progress on implementation of title I (Medi-
13 care Prescription Drug Benefit), title II
14 (Medicare Advantage), and title III (Center for Medi-
15 care Choices) of the Act.

16 (2) Any problems that will impede timely imple-
17 mentation of the Act.

18 **SEC. 618. EXTENSION OF MUNICIPAL HEALTH SERVICE**
19 **DEMONSTRATION PROJECTS.**

20 The last sentence of section 9215(a) of the Consoli-
21 dated Omnibus Budget Reconciliation Act of 1985 (42
22 U.S.C. 1395b–1 note), as previously amended, is amended
23 by striking “December 31, 2004, and inserting “December
24 31, 2006.

SEC. 619. STUDY ON MAKING PRESCRIPTION PHARMACEUTICAL INFORMATION ACCESSIBLE FOR BLIND AND VISUALLY-IMPAIRED INDIVIDUALS.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall undertake a study of how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually-impaired individuals.

(2) STUDY TO INCLUDE EXISTING AND EMERGING TECHNOLOGIES.—The study under paragraph (1) shall include a review of existing and emerging technologies, including assistive technology, that makes essential information on the content and prescribed use of pharmaceutical medicines available in a usable format for blind and visually-impaired individuals.

(b) REPORT.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to Congress on the study required under subsection (a).

(2) CONTENTS OF REPORT.—The report required under subsection (a) shall include rec-

1 ommendations for the implementation of usable for-
 2 mats for making prescription pharmaceutical infor-
 3 mation available to blind and visually-impaired indi-
 4 viduals and an estimate of the costs associated with
 5 the implementation of each format.

6 **SEC. 620. HEALTH CARE THAT WORKS FOR ALL AMERI-**
 7 **CANS-CITIZENS HEALTH CARE WORKING**
 8 **GROUP.**

9 (a) FINDINGS.—Congress finds the following:

10 (1) In order to improve the health care system,
 11 the American public must engage in an informed na-
 12 tional public debate to make choices about the serv-
 13 ices they want covered, what health care coverage
 14 they want, and how they are willing to pay for cov-
 15 erage.

16 (2) More than a trillion dollars annually is
 17 spent on the health care system, yet—

18 (A) 41,000,000 Americans are uninsured;

19 (B) insured individuals do not always have
 20 access to essential, effective services to improve
 21 and maintain their health; and

22 (C) employers, who cover over 170,000,000
 23 Americans, find providing coverage increasingly
 24 difficult because of rising costs and double digit
 25 premium increases.

1 (3) Despite increases in medical care spending
2 that are greater than the rate of inflation, popu-
3 lation growth, and Gross Domestic Product growth,
4 there has not been a commensurate improvement in
5 our health status as a nation.

6 (4) Health care costs for even just 1 member
7 of a family can be catastrophic, resulting in medical
8 bills potentially harming the economic stability of
9 the entire family.

10 (5) Common life occurrences can jeopardize the
11 ability of a family to retain private coverage or jeop-
12 ardize access to public coverage.

13 (6) Innovations in health care access, coverage,
14 and quality of care, including the use of technology,
15 have often come from States, local communities, and
16 private sector organizations, but more creative poli-
17 cies could tap this potential.

18 (7) Despite our Nation's wealth, the health care
19 system does not provide coverage to all Americans
20 who want it.

21 (b) PURPOSES.—The purposes of this Act are—

22 (1) to provide for a nationwide public debate
23 about improving the health care system to provide
24 every American with the ability to obtain quality, af-
25 fordable health care coverage; and

1 (2) to provide for a vote by Congress on the
2 recommendations that result from the debate.

3 (c) ESTABLISHMENT.—The Secretary, acting
4 through the Agency for Healthcare Research and Quality,
5 shall establish an entity to be known as the Citizens'
6 Health Care Working Group (referred to in this Act as
7 the “Working Group”).

8 (d) APPOINTMENT.—Not later than 45 days after the
9 date of enactment of this Act, the Speaker and Minority
10 Leader of the House of Representatives and the Majority
11 Leader and Minority Leader of the Senate (in this section
12 referred to as the “leadership”) shall each appoint individ-
13 uals to serve as members of the Working Group in accord-
14 ance with subsections (e), (f), and (g).

15 (e) MEMBERSHIP CRITERIA.—

16 (1) APPOINTED MEMBERS.—

17 (A) SEPARATE APPOINTMENTS.—The
18 Speaker of the House of Representatives jointly
19 with the Minority Leader of the House of Rep-
20 resentatives, and the Majority Leader of the
21 Senate jointly with the Minority Leader of the
22 Senate, shall each appoint 1 member of the
23 Working Group described in subparagraphs
24 (A), (G), (J), (K), and (M) of paragraph (2).

(B) JOINT APPOINTMENTS.—Members of the Working Group described in subparagraphs (B), (C), (D), (E), (F), (I), and (N) of paragraph (2) shall be appointed jointly by the leadership.

(C) COMBINED APPOINTMENTS.—Members of the Working Group described in subparagraphs (H) and (L) shall be appointed in the following manner:

(i) One member of the Working Group in each of such subparagraphs shall be appointed jointly by the leadership.

(ii) The remaining appointments of the members in each of such subparagraphs shall be divided equally such that the Speaker of the House of Representatives jointly with the Minority Leader of the House of Representatives, and the Majority Leader of the Senate jointly with the Minority Leader of the Senate each appoint an equal number of members.

(2) CATEGORIES OF APPOINTED MEMBERS.—Members of the Working Group shall be appointed as follows:

1 (A) 2 members shall be patients or family
2 members of patients who, at least 1 year prior
3 to the date of enactment of this Act, have had
4 no health insurance.

5 (B) 1 member shall be a representative of
6 children.

7 (C) 1 member shall be a representative of
8 the mentally ill.

9 (D) 1 member shall be a representative of
10 the disabled.

11 (E) 1 member shall be over the age of 65
12 and a beneficiary under the medicare program
13 established under title XVIII of the Social Se-
14 curity Act (42 U.S.C. 1395 et seq.).

15 (F) 1 member shall be a recipient of bene-
16 fits under the medicaid program under title
17 XIX of the Social Security Act (42 U.S.C. 1396
18 et seq.).

19 (G) 2 members shall be State health offi-
20 cials.

21 (H) 3 members shall be employers, includ-
22 ing—

23 (i) 1 large employer (an employer who
24 employed 50 or more employees on busi-
25 ness days during the preceding calendar

1 first year and who employed at least 50 employ-
2 ees on the first of the year);

3 (ii) 1 small employer (an employer
4 who employed an average of at least 2 em-
5 ployees but less than 50 employees on
6 business days in the preceding calendar
7 year and who employs at least 2 employees
8 on the first of the year); and (i) . . . 8

9 (iii) 1 multi-state employer. how 9

10 (I) 1 member shall be a representative of
11 labor. determination over and with 11

12 (J) 2 members shall be health insurance
13 issuers. and (b) (2) (b) (2) 13

14 (K) 2 members shall be health care pro-
15 viders. a. 15

16 (L) 5 members shall be appointed as fol-
17 lows: — 17

18 (i) 1 economist. 18 (1) 18

19 (ii) 1 academician. 19 19

20 (iii) 1 health policy researcher. 20

21 (iv) 1 individual with expertise in
22 pharmacoeconomics. 22 22

23 (v) 1 health technology expert.

24 (M) 2 members shall be representatives of
25 community leaders who have developed State or

1 local community solutions to the problems ad-
2 dressed by the Working Group.

3 (N) 1 member shall be a representative of
4 a medical school.

5 (3) SECRETARY.—The Secretary, or the des-
6 ignee of the Secretary, shall be a member of the
7 Working Group.

8 (f) PROHIBITED APPOINTMENTS.—Members of the
9 Working Group shall not include members of Congress or
10 other elected government officials (Federal, State, or
11 local) other than those individuals specified in subsection
12 (e). To the extent possible, individuals appointed to the
13 Working Group shall have used the health care system
14 within the previous 2 years and shall not be paid employ-
15 ees or representatives of associations or advocacy organi-
16 zations involved in the health care system.

17 (g) APPOINTMENT CRITERIA.—

18 (1) HOUSE OF REPRESENTATIVES.—The
19 Speaker and Minority Leader of the House of Rep-
20 resentatives shall make the appointments described
21 in subsection (d) in consultation with the chair-
22 person and ranking member of the following commit-
23 tees of the House of Representatives:

24 (A) The Committee on Ways and Means.

(B) The Committee on Energy and Commerce.

(C) The Committee on Education and the Workforce.

(2) SENATE.—The Majority Leader and Minority Leader of the Senate shall make the appointments described in subsection (d) in consultation with the chairperson and ranking member of the following committees of the Senate:

(A) The Committee on Finance.

(B) The Committee on Health, Education, Labor, and Pensions.

(h) PERIOD OF APPOINTMENT.—Members of the Working Group shall be appointed for a term of 2 years. Such term is renewable and any vacancies shall not affect the power and duties of the Working Group but shall be filled in the same manner as the original appointment.

(i) APPOINTMENT OF THE CHAIRPERSON.—Not later than 15 days after the date on which all members of the Working Group have been appointed under subsection (d), the leadership shall make a joint designation of the chairperson of the Working Group. If the leadership fails to make such designation within such time period, the Working Group Members shall, not later than 10 days after

1 the end of such time period, designate a chairperson by
2 majority vote.

3 (j) SUBCOMMITTEES.—The Working Group may es-
4 tablish subcommittees if doing so increases the efficiency
5 of the Working Group in completing its tasks.

6 (k) DUTIES.—

7 (1) HEARINGS.—Not later than 90 days after
8 the date of appointment of the chairperson under
9 subsection (i), the Working Group shall hold hear-
10 ings to examine—

11 (A) the capacity of the public and private
12 health care systems to expand coverage options;

13 (B) the cost of health care and the effec-
14 tiveness of care provided at all stages of dis-
15 ease;

16 (C) innovative State strategies used to ex-
17 pand health care coverage and lower health care
18 costs;

19 (D) local community solutions to accessing
20 health care coverage;

21 (E) efforts to enroll individuals currently
22 eligible for public or private health care cov-
23 erage;

24 (F) the role of evidence-based medical
25 practices that can be documented as restoring,

maintaining, or improving a patient's health,
and the use of technology in supporting pro-
viders in improving quality of care and lowering
costs; and

(G) strategies to assist purchasers of
health care, including consumers, to become
more aware of the impact of costs, and to lower
the costs of health care.

(2) ADDITIONAL HEARINGS.—The Working
Group may hold additional hearings on subjects
other than those listed in paragraph (1) so long as
such hearings are determined to be necessary by the
Working Group in carrying out the purposes of this
Act. Such additional hearings do not have to be
completed within the time period specified in para-
graph (1) but shall not delay the other activities of
the Working Group under this section.

(3) THE HEALTH REPORT TO THE AMERICAN
PEOPLE.—Not later than 90 days after the hearings
described in paragraphs (1) and (2) are completed,
the Working Group shall prepare and make available
to health care consumers through the Internet and
other appropriate public channels, a report to be en-
titled, "The Health Report to the American People".

1 Such report shall be understandable to the general
2 public and include—

3 (A) a summary of—

4 (i) health care and related services
5 that may be used by individuals through-
6 out their life span;

7 (ii) the cost of health care services
8 and their medical effectiveness in providing
9 better quality of care for different age
10 groups;

11 (iii) the source of coverage and pay-
12 ment, including reimbursement, for health
13 care services;

14 (iv) the reasons people are uninsured
15 or underinsured and the cost to taxpayers,
16 purchasers of health services, and commu-
17 nities when Americans are uninsured or
18 underinsured;

19 (v) the impact on health care out-
20 comes and costs when individuals are
21 treated in all stages of disease;

22 (vi) health care cost containment
23 strategies; and

24 (vii) information on health care needs
25 that need to be addressed;

1 (B) examples of community strategies to
2 provide health care coverage or access;

3 (C) information on geographic-specific
4 issues relating to health care;

5 (D) information concerning the cost of
6 care in different settings, including institu-
7 tional-based care and home and community-
8 based care;

9 (E) a summary of ways to finance health
10 care coverage; and

11 (F) the role of technology in providing fu-
12 ture health care including ways to support the
13 information needs of patients and providers.

14 (4) COMMUNITY MEETINGS.—

15 (A) IN GENERAL.—Not later than 1 year
16 after the date of enactment of this Act, the
17 Working Group shall initiate health care com-
18 munity meetings throughout the United States
19 (in this section referred to as “community
20 meetings”). Such community meetings may be
21 geographically or regionally based and shall be
22 completed within 180 days after the initiation
23 of the first meeting.

24 (B) NUMBER OF MEETINGS.—The Work-
25 ing Group shall hold a sufficient number of

1 community meetings in order to receive infor-
2 mation that reflects—

3 (i) the geographic differences through-
4 out the United States;

5 (ii) diverse populations; and

6 (iii) a balance among urban and rural
7 populations.

8 (C) MEETING REQUIREMENTS.—

9 (i) FACILITATOR.—A State health of-
10 ficer may be the facilitator at the commu-
11 nity meetings.

12 (ii) ATTENDANCE.—At least 1 mem-
13 ber of the Working Group shall attend and
14 serve as chair of each community meeting.
15 Other members may participate through
16 interactive technology.

17 (iii) TOPICS.—The community meet-
18 ings shall, at a minimum, address the fol-
19 lowing issues:

20 (I) The optimum way to balance
21 costs and benefits so that affordable
22 health coverage is available to as
23 many people as possible.

24 (II) The identification of services
25 that provide cost-effective, essential

health care services to maintain and improve health and which should be included in health care coverage.

(III) The cost of providing increased benefits.

(IV) The mechanisms to finance health care coverage, including defining the appropriate financial role for individuals, businesses, and government.

(iv) INTERACTIVE TECHNOLOGY.—

The Working Group may encourage public participation in community meetings through interactive technology and other means as determined appropriate by the Working Group.

(D) INTERIM REQUIREMENTS.—Not later than 180 days after the date of completion of the community meetings, the Working Group shall prepare and make available to the public through the Internet and other appropriate public channels, an interim set of recommendations on health care coverage and ways to improve and strengthen the health care system based on the information and preferences ex-

1 pressed at the community meetings. There shall
2 be a 90-day public comment period on such rec-
3 ommendations.

4 (1) RECOMMENDATIONS.—Not later than 120 days
5 after the expiration of the public comment period de-
6 scribed in subsection (k)(4)(D), the Working Group shall
7 submit to Congress and the President a final set of rec-
8 ommendations.

9 (m) ADMINISTRATION.—

10 (1) EXECUTIVE DIRECTOR.—There shall be an
11 Executive Director of the Working Group who shall
12 be appointed by the chairperson of the Working
13 Group in consultation with the members of the
14 Working Group.

15 (2) COMPENSATION.—While serving on the
16 business of the Working Group (including travel
17 time), a member of the Working Group shall be enti-
18 tled to compensation at the per diem equivalent of
19 the rate provided for level IV of the Executive
20 Schedule under section 5315 of title 5, United
21 States Code, and while so serving away from home
22 and the member's regular place of business, a mem-
23 ber may be allowed travel expenses, as authorized by
24 the chairperson of the Working Group. For purposes
25 of pay and employment benefits, rights, and privi-

leges, all personnel of the Working Group shall be treated as if they were employees of the Senate.

(3) INFORMATION FROM FEDERAL AGENCIES.—

The Working Group may secure directly from any Federal department or agency such information as the Working Group considers necessary to carry out this Act. Upon request of the Working Group, the head of such department or agency shall furnish such information.

(4) POSTAL SERVICES.—The Working Group

may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(n) DETAIL.—Not more than 10 Federal Government

employees employed by the Department of Labor and 10 Federal Government employees employed by the Department of Health and Human Services may be detailed to the Working Group under this section without further reimbursement. Any detail of an employee shall be without interruption or loss of civil service status or privilege.

(o) TEMPORARY AND INTERMITTENT SERVICES.—

The chairperson of the Working Group may procure temporary and intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals which do not exceed the daily equivalent of the annual rate of

1 basic pay prescribed for level V of the Executive Schedule
2 under section 5316 of such title.

3 (p) ANNUAL REPORT.—Not later than 1 year after
4 the date of enactment of this Act, and annually thereafter
5 during the existence of the Working Group, the Working
6 Group shall report to Congress and make public a detailed
7 description of the expenditures of the Working Group used
8 to carry out its duties under this section.

9 (q) SUNSET OF WORKING GROUP.—The Working
10 Group shall terminate when the report described in sub-
11 section (l) is submitted to Congress.

12 (r) ADMINISTRATION REVIEW AND COMMENTS.—Not
13 later than 45 days after receiving the final recommenda-
14 tions of the Working Group under subsection (l), the
15 President shall submit a report to Congress which shall
16 contain—

17 (1) additional views and comments on such rec-
18 ommendations; and

19 (2) recommendations for such legislation and
20 administrative actions as the President considers ap-
21 propriate.

22 (s) REQUIRED CONGRESSIONAL ACTION.—Not later
23 than 45 days after receiving the report submitted by the
24 President under subsection (r), each committee of jurisdic-
25 tion of Congress shall hold at least 1 hearing on such re-

1 port and on the final recommendations of the Working
2 Group submitted under subsection (l).

3 (t) AUTHORIZATION OF APPROPRIATIONS.—

4 (1) IN GENERAL.—There are authorized to be
5 appropriated to carry out this Act, other than sub-
6 section (k)(3), \$3,000,000 for each of fiscal years
7 2004, 2005, and 2006.

8 (2) HEALTH REPORT TO THE AMERICAN PEO-
9 PLE.—There are authorized to be appropriated for
10 the preparation and dissemination of the Health Re-
11 port to the American People described in subsection
12 (k)(3), such sums as may be necessary for the fiscal
13 year in which the report is required to be submitted.

14 **SEC. 621. GAO STUDY OF PHARMACEUTICAL PRICE CON-**
15 **TROLS AND PATENT PROTECTIONS IN THE G-**
16 **7 COUNTRIES.**

17 (a) STUDY.—The Comptroller General of the United
18 States shall conduct a study of price controls imposed on
19 pharmaceuticals in France, Germany, Italy, Japan, the
20 United Kingdom and Canada to review the impact such
21 regulations have on consumers, including American con-
22 sumers, and on innovation in medicine. Such study shall
23 include—

24 (1) the pharmaceutical price control structure
25 in each country for a wide range of pharmaceuticals,

1 compared with average pharmaceutical prices paid
 2 by Americans covered by private sector health insur-
 3 ance;

4 (2) the proportion of the cost for innovation
 5 borne by American consumers, compared with con-
 6 sumers in the other six countries;

7 (3) a review of how closely the observed prices
 8 in regulated markets correspond to the prices that
 9 efficiently distribute common costs of production
 10 (“Ramsey prices”);

11 (4) a review of any peer-reviewed literature that
 12 might show the health consequences to patients in
 13 the listed countries that result from the absence or
 14 delayed introduction of medicines, including the cost
 15 of not having access to medicines, in terms of lower
 16 life expectancy and lower quality of health;

17 (5) the impact on American consumers, in
 18 terms of reduced research into new or improved
 19 pharmaceuticals (including the cost of delaying the
 20 introduction of a significant advance in certain
 21 major diseases), if similar price controls were adopt-
 22 ed in the United States;

23 (6) the existing standards under international
 24 conventions, including the World Trade Organization
 25 and the North American Free Trade Agreement, re-

garding regulated pharmaceutical prices, including any restrictions on anti-competitive laws that might apply to price regulations and how economic harm caused to consumers in markets without price regulations may be remedied;

(7) in parallel trade regimes, how much of the price difference between countries in the European Union is captured by middlemen and how much goes to benefit patients and health systems where parallel importing is significant; and

(8) how much cost is imposed on the owner of a property right from counterfeiting and from international violation of intellectual property rights for prescription medicines.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the study conducted under subsection (a).

SEC. 622. SENSE OF THE SENATE CONCERNING MEDICARE PAYMENT UPDATE FOR PHYSICIANS AND OTHER HEALTH PROFESSIONALS.

(a) FINDINGS.—The Senate makes the following findings:

(1) The formula by which medicare payments are updated each year for services furnished by phy-

1 sicians and other health professionals is fundamen-
2 tally flawed.

3 (2) The flawed physician payment update for-
4 mula is causing a continuing physician payment cri-
5 sis, and, without congressional action, medicare pay-
6 ment rates for physicians and other practitioners are
7 predicted to fall by 4.2 percent in 2004.

8 (3) A physician payment cut in 2004 would be
9 the fifth cut since 1991, and would be on top of a
10 5.4 percent cut in 2002, with additional cuts esti-
11 mated for 2005, 2006, and 2007; from 1991–2003,
12 payment rates for physicians and health profes-
13 sionals fell 14 percent behind practice cost inflation
14 as measured by medicare's own conservative esti-
15 mates.

16 (4) The sustainable growth rate (SGR) expendi-
17 ture target, which is the basis for the physician pay-
18 ment update, is linked to the gross domestic product
19 and penalizes physicians and other practitioners for
20 volume increases that they cannot control and that
21 the Government actively promotes through new cov-
22 erage decisions, quality improvement activities and
23 other initiatives that, while beneficial to patients, are
24 not reflected in the SGR.

1 (b) SENSE OF THE SENATE.—It is the sense of the
2 Senate that medicare beneficiary access to quality care
3 may be compromised if Congress does not take action to
4 prevent cuts next year and the following that result from
5 the SGR formula.

6 **SEC. 623. RESTORATION OF FEDERAL HOSPITAL INSUR-**
7 **ANCE TRUST FUND.**

8 (a) DEFINITIONS.—In this section:

9 (1) CLERICAL ERROR.—The term “clerical
10 error” means the failure that occurred on April 15,
11 2001, to have transferred the correct amount from
12 the general fund of the Treasury to the Trust Fund.

13 (2) TRUST FUND.—The term “Trust Fund”
14 means the Federal Hospital Insurance Trust Fund
15 established under section 1817 of the Social Security
16 Act (42 U.S.C. 1395i).

17 (b) CORRECTION OF TRUST FUND HOLDINGS.—

18 (1) IN GENERAL.—Not later than 120 days
19 after the date of enactment of this Act, the Sec-
20 retary of the Treasury shall take the actions de-
21 scribed in paragraph (2) with respect to the Trust
22 Fund with the goal being that, after such actions
23 are taken, the holdings of the Trust Fund will rep-
24 licate, to the extent practicable in the judgment of
25 the Secretary of the Treasury, in consultation with

1 the Secretary of Health and Human Services, the
 2 holdings that would have been held by the Trust
 3 Fund if the clerical error had not occurred.

4 (2) OBLIGATIONS ISSUED AND REDEEMED.—

5 The Secretary of the Treasury shall—

6 (A) issue to the Trust Fund obligations
 7 under chapter 31 of title 31, United States
 8 Code, that bear issue dates, interest rates, and
 9 maturity dates that are the same as those for
 10 the obligations that—

11 (i) would have been issued to the
 12 Trust Fund if the clerical error had not oc-
 13 curred; or

14 (ii) were issued to the Trust Fund
 15 and were redeemed by reason of the cler-
 16 ical error; and

17 (B) redeem from the Trust Fund obliga-
 18 tions that would have been redeemed from the
 19 Trust Fund if the clerical error had not oc-
 20 curred.

21 (c) APPROPRIATION.—Not later than 120 days after
 22 the date of enactment of this Act, there is appropriated
 23 to the Trust Fund, out of any money in the Treasury not
 24 otherwise appropriated, an amount determined by the Sec-
 25 retary of the Treasury, in consultation with the Secretary

1 of Health and Human Services, to be equal to the interest
 2 income lost by the Trust Fund through the date on which
 3 the appropriation is being made as a result of the clerical
 4 error.

5 **SEC. 624. SAFETY NET ORGANIZATIONS AND PATIENT ADVI-**
 6 **SORY COMMISSION.**

7 (a) IN GENERAL.—Title XI (42 U.S.C. 1320 et seq.)
 8 is amended by adding at the end the following new part:

9 “PART D—SAFETY NET ORGANIZATIONS AND PATIENT
 10 ADVISORY COMMISSION

11 “SAFETY NET ORGANIZATIONS AND PATIENT ADVISORY
 12 COMMISSION

13 “SEC. 1181. (a) ESTABLISHMENT.—There is hereby
 14 established the Safety Net Organizations and Patient Ad-
 15 visory Commission (in this section referred to as the ‘Com-
 16 mission’).

17 “(b) REVIEW OF HEALTH CARE SAFETY NET PRO-
 18 GRAMS AND REPORTING REQUIREMENTS.—

19 “(1) REVIEW.—The Commission shall conduct
 20 an ongoing review of the health care safety net pro-
 21 grams (as described in paragraph (3)(C)) by—

22 “(A) monitoring each health care safety
 23 net program to document and analyze the ef-
 24 fects of changes in these programs on the core
 25 health care safety net;

1 “(B) evaluating the impact of the Emer-
 2 gency Medical Treatment and Labor Act, the
 3 Health Insurance Portability and Accountability
 4 Act of 1996, the Balanced Budget Act of 1997,
 5 the Medicare, Medicaid, and SCHIP Balanced
 6 Budget Refinement Act of 1999, the Medicare,
 7 Medicaid, and SCHIP Benefits Protection and
 8 Improvement Act of 2000, Prescription Drug
 9 and Medicare Improvement Act of 2003, and
 10 other forces on the capacity of the core health
 11 care safety net to continue their roles in the
 12 core health care safety net system to care for
 13 uninsured individuals, medicaid beneficiaries,
 14 and other vulnerable populations;

15 “(C) monitoring existing data sets to as-
 16 sess the status of the core health care safety
 17 net and health outcomes for vulnerable popu-
 18 lations;

19 “(D) wherever possible, linking and inte-
 20 grating existing data systems to enhance the
 21 ability of the core health care safety net to
 22 track changes in the status of the core health
 23 care safety net and health outcomes for vulner-
 24 able populations;

1 “(E) supporting the development of new
2 data systems where existing data are insuffi-
3 cient or inadequate;

4 “(F) developing criteria and indicators of
5 impending core health care safety net failure;

6 “(G) establishing an early-warning system
7 to identify impending failures of core health
8 care safety net systems and providers;

9 “(H) providing accurate and timely infor-
10 mation to Federal, State, and local policy-
11 makers on the indicators that may lead to the
12 failure of the core health care safety net and an
13 estimate of the projected consequences of such
14 failures and the impact of such a failure on the
15 community;

16 “(I) monitoring and providing oversight for
17 the transition of individuals receiving supple-
18 mental security income benefits, medical assist-
19 ance under title XIX, or child health assistance
20 under title XXI who enroll with a managed care
21 entity (as defined in section 1932(a)(1)(B)), in-
22 cluding the review of—

23 “(i) the degree to which health plans
24 have the capacity (including case manage-
25 ment and management information system

1 infrastructure) to provide quality managed

2 health care services to such an individual;

3 “(ii) the degree to which these plans

4 may be overburdened by adverse selection;

5 and

6 “(iii) the degree to which emergency

7 departments are used by enrollees of these

8 plans; and

9 “(J) identifying and disseminating the best

10 practices for more effective application of the

11 lessons that have been learned.

12 “(2) REPORTS.—

13 “(A) ANNUAL REPORTS.—Not later than

14 June 1 of each year (beginning with 2005), the

15 Commission shall, based on the review con-

16 ducted under paragraph (1), submit to the ap-

17 propriate committees of Congress a report on—

18 “(i) the health care needs of the unin-

19 sured; and

20 “(ii) the financial and infrastructure

21 stability of the Nation’s core health care

22 safety net.

23 “(B) AGENDA AND ADDITIONAL RE-

24 VIEWS.—

“(i) AGENDA.—The Chair of the Commission shall consult periodically with the Chairpersons and Ranking Minority Members of the appropriate committees of Congress regarding the Commission’s agenda and progress toward achieving the agenda. *§ 101(b)(1)(A)*

“(ii) ADDITIONAL REVIEWS.—The Commission shall conduct additional reviews and submit additional reports to the appropriate committees of Congress on topics relating to the health care safety net programs under the following circumstances: *§ 101(b)(1)(B)*

“(I) If requested by the Chairpersons or Ranking Minority Members of such committees. *§ 101(b)(1)(B)(i)*

“(II) If the Commission deems such additional reviews and reports appropriate. *§ 101(b)(1)(B)(ii)*

“(C) AVAILABILITY OF REPORTS.—The Commission shall transmit to the Comptroller General and the Secretary a copy of each report submitted under this subsection and shall make such reports available to the public. *§ 101(b)(2)*

1 “(3) DEFINITIONS.—In this section:

2 “(A) APPROPRIATE COMMITTEES OF CON-
3 GRESS.—The term ‘appropriate committees of
4 Congress’ means the Committees on Ways and
5 Means and Energy and Commerce of the House
6 of Representatives and the Committees on Fi-
7 nance and Health, Education, Labor, and Pen-
8 sions of the Senate.

9 “(B) CORE HEALTH CARE SAFETY NET.—
10 The term ‘core health care safety net’ means
11 any health care provider that—

12 “(i) by legal mandate or explicitly
13 adopted mission, offers access to health
14 care services to patients, regardless of the
15 ability of the patient to pay for such serv-
16 ices; and

17 “(ii) has a case mix that is substan-
18 tially comprised of patients who are unin-
19 sured, covered under the medicaid pro-
20 gram, covered under any other public
21 health care program, or are otherwise vul-
22 nerable populations.

23 Such term includes disproportionate share hos-
24 pitals, Federally qualified health centers, other
25 Federal, State, and locally supported clinics,

rural health clinics, local health departments,
and providers covered under the Emergency
Medical Treatment and Labor Act.

“(C) HEALTH CARE SAFETY NET PRO-
GRAMS.—The term ‘health care safety net pro-
grams’ includes the following:

“(i) MEDICAID.—The medicaid pro-
gram under title XIX.

“(ii) SCHIP.—The State children’s
health insurance program under title XXI.

“(iii) MATERNAL AND CHILD HEALTH
SERVICES BLOCK GRANT PROGRAM.—The
maternal and child health services block
grant program under title V.

“(iv) FQHC PROGRAMS.—Each feder-
ally funded program under which a health
center (as defined in section 330(1) of the
Public Health Service Act), a Federally
qualified health center (as defined in sec-
tion 1861(aa)(4)), or a Federally-qualified
health center (as defined in section
1905(l)(2)(B)) receives funds.

“(v) RHC PROGRAMS.—Each feder-
ally funded program under which a rural

1 health clinic (as defined in section
2 1861(aa)(4) or 1905(l)(1)) receives funds.

3 “(vi) DSH PAYMENT PROGRAMS.—
4 Each federally funded program under
5 which a disproportionate share hospital re-
6 ceives funds.

7 “(vii) EMERGENCY MEDICAL TREAT-
8 MENT AND ACTIVE LABOR ACT.—All care
9 provided under section 1867 for the unin-
10 sured, underinsured, beneficiaries under
11 title XIX, and other vulnerable individuals.

12 “(viii) OTHER HEALTH CARE SAFETY
13 NET PROGRAMS.—Such term also includes
14 any other health care program that the
15 Commission determines to be appropriate.

16 “(D) VULNERABLE POPULATIONS.—The
17 term ‘vulnerable populations’ includes unin-
18 sured and underinsured individuals, low-income
19 individuals, farm workers, homeless individuals,
20 individuals with disabilities, individuals with
21 HIV or AIDS, and such other individuals as the
22 Commission may designate.

23 “(c) MEMBERSHIP.—

24 “(1) NUMBER AND APPOINTMENT.—The Com-
25 mission shall be composed of 13 members appointed

by the Comptroller General of the United States (in this section referred to as the 'Comptroller General'), in consultation with the appropriate committees of Congress.

“(2) QUALIFICATIONS.—

“(A) IN GENERAL.—The membership of the Commission shall include individuals with national recognition for their expertise in health finance and economics, health care safety net research and program management, actuarial science, health facility management, health plans and integrated delivery systems, reimbursement of health facilities, allopathic and osteopathic medicine (including emergency medicine), and other providers of health services, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives.

“(B) INCLUSION.—The membership of the Commission shall include health professionals, employers, third-party payers, individuals skilled in the conduct and interpretation of biomedical, health services, and health economics research and expertise in outcomes and effec-

tiveness research and technology assessment.
Such membership shall also include recipients of care from core health care safety net and individuals who provide and manage the delivery of care by the core health care safety net.

“(C) MAJORITY NONPROVIDERS.—Individuals who are directly involved in the provision, or management of the delivery, of items and services covered under the health care safety net programs shall not constitute a majority of the membership of the Commission.

“(D) ETHICAL DISCLOSURE.—The Comptroller General shall establish a system for public disclosure by members of the Commission of financial and other potential conflicts of interest relating to such members.

“(3) TERMS.—

“(A) IN GENERAL.—The terms of members of the Commission shall be for 3 years except that of the members first appointed, the Comptroller General shall designate—

“(i) four to serve a term of 1 year;

“(ii) four to serve a term of 2 years;

and

“(iii) five to serve a term of 3 years.

“(B) VACANCIES.—

“(i) IN GENERAL.—A vacancy in the Commission shall be filled in the same manner in which the original appointment was made.

“(ii) APPOINTMENT.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member’s predecessor was appointed shall be appointed only for the remainder of that term.

“(iii) TERMS.—A member may serve after the expiration of that member’s term until a successor has taken office.

“(4) COMPENSATION.—

“(A) MEMBERS.—While serving on the business of the Commission (including travel time), a member of the Commission—

“(i) shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code; and

“(ii) while so serving away from home and the member’s regular place of busi-

1 ness, may be allowed travel expenses, as
2 authorized by the Commission.

3 “(B) TREATMENT.—For purposes of pay
4 (other than pay of members of the Commission)
5 and employment benefits, rights, and privileges,
6 all personnel of the Commission shall be treated
7 as if they were employees of the United States
8 Senate.

9 “(5) CHAIR; VICE CHAIR.—The Comptroller
10 General shall designate a member of the Commis-
11 sion, at the time of appointment of the member as
12 Chair and a member as Vice Chair for that term of
13 appointment, except that in the case of vacancy of
14 the Chair or Vice Chair, the Comptroller General
15 may designate another member for the remainder of
16 that member’s term.

17 “(6) MEETINGS.—The Commission shall meet
18 at the call of the Chair or upon the written request
19 of a majority of its members.

20 “(d) DIRECTOR AND STAFF; EXPERTS AND CON-
21 SULTANTS.—Subject to such review as the Comptroller
22 General determines necessary to ensure the efficient ad-
23 ministration of the Commission, the Commission may—

24 “(1) employ and fix the compensation of an Ex-
25 ecutive Director (subject to the approval of the

1 Comptroller General) and such other personnel as
 2 may be necessary to carry out the duties of the
 3 Commission under this section (without regard to
 4 the provisions of title 5, United States Code, gov-
 5 erning appointments in the competitive service);

6 “(2) seek such assistance and support as may
 7 be required in the performance of the duties of the
 8 Commission under this section from appropriate
 9 Federal departments and agencies; for

10 “(3) enter into contracts or make other ar-
 11 rangements, as may be necessary for the conduct of
 12 the work of the Commission (without regard to sec-
 13 tion 3709 of the Revised Statutes (41 U.S.C. 5));

14 “(4) make advance, progress, and other pay-
 15 ments which relate to the work of the Commission;

16 “(5) provide transportation and subsistence for
 17 persons serving without compensation; and

18 “(6) prescribe such rules and regulations as it
 19 deems necessary with respect to the internal organi-
 20 zation and operation of the Commission.

21 “(e) POWERS.— *can be removed*

22 “(1) OBTAINING OFFICIAL DATA.—

23 “(A) IN GENERAL.—The Commission may
 24 secure directly from any department or agency
 25 of the United States information necessary for

1 the Commission to carry the duties under this
2 section.

3 “(B) REQUEST OF CHAIR.—Upon request
4 of the Chair, the head of that department or
5 agency shall furnish that information to the
6 Commission on an agreed upon schedule.

7 “(2) DATA COLLECTION.—In order to carry out
8 the duties of the Commission under this section, the
9 Commission shall—

10 “(A) use existing information, both pub-
11 lished and unpublished, where possible, collected
12 and assessed either by the staff of the Commis-
13 sion or under other arrangements made in ac-
14 cordance with this section;

15 “(B) carry out, or award grants or con-
16 tracts for, original research and experimen-
17 tation, where existing information is inad-
18 equate; and

19 “(C) adopt procedures allowing any inter-
20 ested party to submit information for the Com-
21 mission’s use in making reports and rec-
22 ommendations.

23 “(3) ACCESS OF GAO TO INFORMATION.—The
24 Comptroller General shall have unrestricted access
25 to all deliberations, records, and nonproprietary data

that pertains to the work of the Commission, immediately upon request. The expense of providing such information shall be borne by the General Accounting Office.

“(4) PERIODIC AUDIT.—The Commission shall be subject to periodic audit by the Comptroller General.

“(f) APPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) does not apply to the Commission.

“(g) AUTHORIZATION OF APPROPRIATIONS.—

“(1) REQUEST FOR APPROPRIATIONS.—The Commission shall submit requests for appropriations in the same manner as the Comptroller General submits requests for appropriations, but amounts appropriated for the Commission shall be separate from amounts appropriated for the Comptroller General.

“(2) AUTHORIZATION.—There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section.”.

(b) EFFECTIVE DATE.—The Comptroller General of the United States shall appoint the initial members of the Safety Net Organizations and Patient Advisory Commis-

1 sion established under subsection (a) not later than June
2 1, 2004.

3 **SEC. 625. URBAN HEALTH PROVIDER ADJUSTMENT.**

4 (a) IN GENERAL.—Beginning with fiscal year 2004,
5 notwithstanding section 1923(f) of the Social Security Act
6 (42 U.S.C. 1396r-4(f)) and subject to subsection (c), with
7 respect to a State, payment adjustments made under title
8 XIX of the Social Security Act (42 U.S.C. 1396 et seq.)
9 to a hospital described in subsection (b) shall be made
10 without regard to the DSH allotment limitation for the
11 State determined under section 1923(f) of that Act (42
12 U.S.C. 1396r-4(f)).

13 (b) HOSPITAL DESCRIBED.—A hospital is described
14 in this subsection if the hospital—

15 (1) is owned or operated by a State (as defined
16 for purposes of title XIX of the Social Security Act),
17 or by an instrumentality or a municipal govern-
18 mental unit within a State (as so defined) as of Jan-
19 uary 1, 2003; and

20 (2) is located in Marion County, Indiana.

21 (c) LIMITATION.—The payment adjustment described
22 in subsection (a) for fiscal year 2004 and each fiscal year
23 thereafter shall not exceed 175 percent of the costs of fur-
24 nishing hospital services described in section

1 1923(g)(1)(A) of the Social Security Act (42 U.S.C.
2 1396r-4(g)(1)(A)).

3 **SEC. 626. COMMITTEE ON DRUG COMPOUNDING.**

4 (a) **ESTABLISHMENT.**—The Secretary of Health and
5 Human Services shall establish an Committee on Drug
6 Compounding (referred to in this section as the “Com-
7 mittee”) within the Food and Drug Administration on
8 drug compounding to ensure that patients are receiving
9 necessary, safe and accurate dosages of compounded
10 drugs.

11 (b) **MEMBERSHIP.**—The membership of the Advisory
12 Committee shall be appointed by the Secretary of Health
13 and Human Services and shall include representatives
14 of—

- 15 (1) the National Association of Boards of Phar-
16 macy;
- 17 (2) pharmacy groups;
- 18 (3) physician groups;
- 19 (4) consumer and patient advocate groups;
- 20 (5) the United States Pharmacopoeia; and
- 21 (6) other individuals determined appropriate by
22 the Secretary.

23 (c) **REPORT AND RECOMMENDATIONS.**—Not later
24 than 1 year after the date of enactment of this Act, the
25 Committee shall submit to the Secretary a report con-

cerning the recommendations of the Committee to improve
and protect patient safety.

(d) **TERMINATION.**—The Committee shall terminate
on the date that is 1 year after the date of enactment
of this Act.

**SEC. 627. SENSE OF THE SENATE CONCERNING THE STRUC-
TURE OF MEDICARE REFORM AND THE PRE-
SCRIPTION DRUG BENEFIT.**

(a) **FINDINGS.**—The Senate makes the following
findings:

(1) America's seniors deserve a fiscally-strong
medicare system that fulfills its promise to them and
future retirees.

(2) The impending retirement of the “baby
boom” generation will dramatically increase the
costs of providing medicare benefits. Medicare costs
will double relative to the size of the economy from
2 percent of GDP today to 4 percent in 2025 and
double again to 8 percent of GDP in 2075. This
growth will accelerate substantially when Congress
adds a necessary prescription drug benefit.

(3) Medicare's current structure does not have
the flexibility to quickly adapt to rapid advances in
modern health care. Medicare lags far behind other
insurers in providing prescription drug coverage, dis-

1 ease management programs, and host of other ad-
2 vances. Reforming medicare to create a more self-
3 adjusting, innovative structure is essential to im-
4 prove medicare's efficiency and the quality of the
5 medical care it provides.

6 (4) Private-sector choice for medicare bene-
7 ficiaries would provide two key benefits: It would be
8 tailored to the needs of America's seniors, not the
9 Government, and would create a powerful incentive
10 for private-sector medicare plans to provide the best
11 quality health care to seniors at the most affordable
12 price.

13 (5) The method by which the national preferred
14 provider organizations in the Federal Employees
15 Health Benefits Program have been reimbursed has
16 proven to be a reliable and successful mechanism for
17 providing Members of Congress and Federal employ-
18 ees with excellent health care choices.

19 (6) Unlike the medicare payment system, which
20 has had to be changed by Congress every few years,
21 the Federal Employees Health Benefits Program
22 has existed for 43 years with minimal changes from
23 Congress.

24 (b) SENSE OF THE SENATE.—It is the sense of the
25 Senate that medicare reform legislation should:

1 (1) Ensure that prescription drug coverage is
2 directed to those who need it most.

3 (2) Provide that Government contributions used
4 to support MedicareAdvantage plans are based on
5 market principles beginning in 2006 to ensure the
6 long- and short-term viability of such options for
7 America's seniors.

8 (3) Develop a payment system for the
9 MedicareAdvantage preferred provider organizations
10 similar to the payment system used for the national
11 preferred provider organizations in the Federal Em-
12 ployees Health Benefits Program.

13 (4) Limit the addition of new unfunded obliga-
14 tions in the medicare program so that the long-term
15 solvency of this important program is not further
16 jeopardized.

17 (5) Incorporate private sector, market-based
18 elements, that do not rely on the inefficient medicare
19 price control structure.

20 (6) Keep the cost of structural changes and
21 new benefits within the \$400,000,000,000 provided
22 for under the current Congressional Budget Resolu-
23 tion for implementing medicare reform and pro-
24 viding a prescription drug benefit.

(7) Preserve the current employer-sponsored retiree health plans and not design a benefit which has the unintended consequences of supplanting private coverage.

(8) Incorporate regulatory reform proposals to eliminate red tape and reduce costs.

(9) Restore the right of medicare beneficiaries and their doctors to work together to provide services, allow private fee for service plans to set their own premiums, and permit seniors to add their own dollars beyond the Government contribution.

SEC. 628. SENSE OF THE SENATE REGARDING THE ESTABLISHMENT OF A NATIONWIDE PERMANENT LIFESTYLE MODIFICATION PROGRAM FOR MEDICARE BENEFICIARIES.

(a) FINDINGS.—Congress finds that:

(1) Heart disease kills more than 500,000 Americans per year.

(2) The number and costs of interventions for the treatment of coronary disease are rising and currently cost the health care system \$58,000,000,000 annually.

(3) The Medicare Lifestyle Modification Program has been operating throughout 12 States and

1 has been demonstrated to reduce the need for coro-
2 nary procedures by 88 percent per year.

3 (4) The Medicare Lifestyle Modification Pro-
4 gram is less expensive to deliver than interventional
5 cardiac procedures and could reduce cardiovascular
6 expenditures by \$36,000,000,000 annually.

7 (5) Lifestyle choices such as diet and exercise
8 affect heart disease and heart disease outcomes by
9 50 percent or greater.

10 (6) Intensive lifestyle interventions which in-
11 clude teams of nurses, doctors, exercise physiolo-
12 gists, registered dietitians, and behavioral health cli-
13 nicians have been demonstrated to reduce heart dis-
14 ease risk factors and enhance heart disease out-
15 comes dramatically.

16 (7) The National Institutes of Health estimates
17 that 17,000,000 Americans have diabetes and the
18 Centers for Disease Control and Prevention esti-
19 mates that the number of Americans who have a di-
20 agnosis of diabetes increased 61 percent in the last
21 decade and is expected to more than double by
22 2050.

23 (8) Lifestyle modification programs are supe-
24 rior to medication therapy for treating diabetes.

(9) Individuals with diabetes are now considered to have coronary disease at the date of diagnosis of their diabetic state.

(10) The Medicare Lifestyle Modification Program has been an effective lifestyle program for the reversal and treatment of heart disease.

(11) Men with prostate cancer have shown significant improvement in prostate cancer markers using a similar approach in lifestyle modification.

(12) These lifestyle changes are therefore likely to affect other chronic disease states, in addition to heart disease.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) the Secretary of Health and Human Services should carry out the demonstration project known as the Lifestyle Modification Program Demonstration, as described in the Health Care Financing Administration Memorandum of Understanding entered into on November 13, 2000, on a permanent basis;

(2) the project should include as many Medicare beneficiaries as would like to participate in the project on a voluntary basis; and

1 (3) the project should be conducted on a na-
2 tional basis.

3 **SEC. 629. SENSE OF THE SENATE ON PAYMENT REDUC-**
4 **TIONS UNDER MEDICARE PHYSICIAN FEE**
5 **SCHEDULE.**

6 (a) FINDINGS.—Congress finds that—

7 (1) the fees medicare pays physicians were re-
8 duced by 5.4 percent across-the-board in 2002;

9 (2) recent action by Congress narrowly averted
10 another across-the-board reduction of 4.4 percent for
11 2003;

12 (3) based on current projections, the Centers
13 for Medicare & Medicaid Services (CMS) estimates
14 that, absent legislative or administrative action, fees
15 will be reduced across-the-board once again in 2004
16 by 4.2 percent;

17 (4) the prospect of continued payment reduc-
18 tions under the medicare physician fee schedule for
19 the foreseeable future threatens to destabilize an im-
20 portant element of the program, namely physician
21 participation and willingness to accept medicare pa-
22 tients;

23 (5) the primary source of this instability is the
24 sustainable growth rate (SGR), a system of annual

1 spending targets for physicians' services under medi-
2 care;

3 (6) the SGR system has a number of defects
4 that result in unrealistically low spending targets,
5 such as the use of the increase in the gross domestic
6 product (GDP) as a proxy for increases in the vol-
7 ume and intensity of services provided by physicians,
8 no tolerance for variance between growth in medi-
9 care beneficiary health care costs and our Nation's
10 GDP, and a requirement for immediate recoupment
11 of the difference;

12 (7) both administrative and legislative action
13 are needed to return stability to the physician pay-
14 ment system;

15 (8) using the discretion given to it by medicare
16 law, CMS has included expenditures for prescription
17 drugs and biologicals administered incident to physi-
18 cians' services under the annual spending targets
19 without making appropriate adjustments to the tar-
20 gets to reflect price increases in these drugs and
21 biologicals or the growing reliance on such therapies
22 in the treatment of medicare patients;

23 (9) between 1996 and 2002, annual medicare
24 spending on these drugs grew from \$1,800,000,000

1 to \$6,200,000,000, or from \$55 per beneficiary to
 2 an estimated \$187 per beneficiary;

3 (10) although physicians are responsible for
 4 prescribing these drugs and biologicals, neither the
 5 price of the drugs and biologicals, nor the standards
 6 of care that encourage their use, are within the con-
 7 trol of physicians; and

8 (11) SGR target adjustments have not been
 9 made for cost increases due to new coverage deci-
 10 sions and new rules and regulations.

11 (b) SENSE OF THE SENATE.—It is the sense of the
 12 Senate that—

13 (1) the Center for Medicare & Medicaid Serv-
 14 ices (CMS) should use its discretion to exclude drugs
 15 and biologicals administered incident to physician
 16 services from the sustainable growth rate (SGR) sys-
 17 tem;

18 (2) CMS should use its discretion to make SGR
 19 target adjustments for new coverage decisions and
 20 new rules and regulations; and

21 (3) in order to provide ample time for Congress
 22 to consider more fundamental changes to the SGR
 23 system, the conferees on the Prescription Drug and
 24 Medicare Improvement Act of 2003 should include
 25 in the conference agreement a provision to establish

a minimum percentage update in physician fees for the next 2 years and should consider adding provisions that would mitigate the swings in payment, such as establishing multi-year adjustments to recoup the variance and creating “tolerance” corridors for variations around the update target trend.

SEC. 630. TEMPORARY SUSPENSION OF OASIS REQUIREMENT FOR COLLECTION OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS.

(a) IN GENERAL.—During the period described in subsection (b), the Secretary may not require, under section 4602(e) of the Balanced Budget Act of 1997 or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not eligible for benefits under either title XVIII or title XIX of the Social Security Act (such information in this section referred to as “non-medicare/medicaid OASIS information”).

(b) PERIOD OF SUSPENSION.—The period described in this subsection—

(1) begins on the date of the enactment of this Act; and

(2) ends on the last day of the 2nd month beginning after the date as of which the Secretary has published final regulations regarding the collection

and use by the Centers for Medicare & Medicaid Services of non-medicare/medicaid OASIS information following the submission of the report required under subsection (c).

(c) REPORT.—

(1) STUDY.—The Secretary shall conduct a study on how non-medicare/medicaid OASIS information is and can be used by large home health agencies. Such study shall examine—

(A) whether there are unique benefits from the analysis of such information that cannot be derived from other information available to, or collected by, such agencies; and

(B) the value of collecting such information by small home health agencies compared to the administrative burden related to such collection.

In conducting the study the Secretary shall obtain recommendations from quality assessment experts in the use of such information and the necessity of small, as well as large, home health agencies collecting such information.

(2) REPORT.—The Secretary shall submit to Congress a report on the study conducted under

paragraph (1) by not later than 18 months after the date of the enactment of this Act. (11)

(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing home health agencies from collecting non-medicare/medicaid OASIS information for their own use. (11)

SEC. 631. EMPLOYER FLEXIBILITY.

(a) MEDICARE.—Nothing in part D of title XVIII of the Social Security Act, as added by section 101, shall be construed as—

(1) preventing employment-based retiree health coverage (as defined in section 1860D–20(e)(4)(B) of such Act, as so added) from providing coverage that is supplemental to the benefits provided under a Medicare Prescription Drug plan under such part or a Medicare Advantage plan under part C of such title, as amended by this Act; or

(2) requiring employment-based retiree health coverage (as so defined) that provides medical benefits to retired participants who are not eligible for medical benefits under title XVIII of the Social Security Act or under a plan maintained by a State or an agency thereof to provide medical benefits, or the same medical benefits, to retired participants who are so eligible.

1 (b) ADEA.—

2 (1) IN GENERAL.—Section 4(l) of the Age Dis-
3 crimination in Employment Act of 1967 (29 U.S.C.
4 623(l)) is amended by adding at the end the fol-
5 lowing:

6 “(4) An employee benefit plan (as defined in
7 section 3(3) of the Employee Retirement Income Se-
8 curity Act of 1974 (29 U.S.C. 1002(3))) shall not be
9 treated as violating subsection (a), (b), (c), or (e)
10 solely because the plan provides medical benefits to
11 retired participants who are not eligible for medical
12 benefits under title XVIII of the Social Security Act
13 (42 U.S.C. 1395 et seq.) or under a plan maintained
14 by a State or an agency thereof, but does not pro-
15 vide medical benefits, or the same medical benefits,
16 to retired participants who are so eligible.”

17 (2) EFFECTIVE DATE.—The amendment made
18 by this subsection shall apply as of the date of the
19 enactment of this Act.

1 **SEC. 632. ONE HUNDRED PERCENT FMAP FOR MEDICAL AS-**
 2 **SISTANCE PROVIDED TO A NATIVE HAWAIIAN**
 3 **THROUGH A FEDERALLY-QUALIFIED HEALTH**
 4 **CENTER OR A NATIVE HAWAIIAN HEALTH**
 5 **CARE SYSTEM UNDER THE MEDICAID PRO-**
 6 **GRAM.**

7 (a) **MEDICAID.**—Section 1905(b) of the Social Secu-
 8 rity Act (42 U.S.C. 1396d(b)) is amended, in the third
 9 sentence, by inserting “, and with respect to medical as-
 10 sistance provided to a Native Hawaiian (as defined in sec-
 11 tion 12 of the Native Hawaiian Health Care Improvement
 12 Act) through a federally-qualified health center or a Na-
 13 tive Hawaiian health care system (as so defined) whether
 14 directly, by referral, or under contract or other arrange-
 15 ment between a federally-qualified health center or a Na-
 16 tive Hawaiian health care system and another health care
 17 provider” before the period.

18 (b) **EFFECTIVE DATE.**—The amendment made by
 19 this section applies to medical assistance provided on or
 20 after the date of enactment of this Act.

21 **SEC. 633. EXTENSION OF MORATORIUM.**

22 (a) **IN GENERAL.**—Section 6408(a)(3) of the Omni-
 23 bus Budget Reconciliation Act of 1989, as amended by
 24 section 13642 of the Omnibus Budget Reconciliation Act
 25 of 1993 and section 4758 of the Balanced Budget Act of
 26 1997, is amended—

1 (1) by striking “until December 31, 2002”, and

2 (2) by striking “Kent Community Hospital

3 Complex in Michigan or.”

4 (b) EFFECTIVE DATES.—

5 (1) PERMANENT EXTENSION.—The amendment
6 made by subsection (a)(1) shall take effect as if in-
7 cluded in the amendment made by section 4758 of
8 the Balanced Budget Act of 1997.

9 (2) MODIFICATION.—The amendment made by
10 subsection (a)(2) shall take effect on the date of en-
11 actment of this Act.

12 **SEC. 634. GAO STUDY OF PHARMACEUTICAL PRICE CON-**
13 **TROLS AND PATENT PROTECTIONS IN THE G-**
14 **7 COUNTRIES.**

15 (a) STUDY.—The Comptroller General of the United
16 States shall conduct a study of price controls imposed on
17 pharmaceuticals in France, Germany, Italy, Japan, the
18 United Kingdom and Canada to review the impact such
19 regulations have on consumers, including American con-
20 sumers, and on innovation in medicine. The study shall
21 include the following:

22 (1) The pharmaceutical price control structure
23 in each country for a wide range of pharmaceuticals,
24 compared with average pharmaceutical prices paid

1 by Americans covered by private sector health insur-
2 ance.

3 (2) The proportion of the cost for innovation
4 borne by American consumers, compared with con-
5 sumers in the other 6 countries.

6 (3) A review of how closely the observed prices
7 in regulated markets correspond to the prices that
8 efficiently distribute common costs of production
9 ("Ramsey prices").

10 (4) A review of any peer-reviewed literature
11 that might show the health consequences to patients
12 in the listed countries that result from the absence
13 or delayed introduction of medicines, including the
14 cost of not having access to medicines, in terms of
15 lower life expectancy and lower quality of health.

16 (5) The impact on American consumers, in
17 terms of reduced research into new or improved
18 pharmaceuticals (including the cost of delaying the
19 introduction of a significant advance in certain
20 major diseases), if similar price controls were adopt-
21 ed in the United States.

22 (6) The existing standards under international
23 conventions, including the World Trade Organization
24 and the North American Free Trade Agreement, re-
25 garding regulated pharmaceutical prices, including

1 any restrictions on anti-competitive laws that might
 2 apply to price regulations and how economic harm
 3 caused to consumers in markets without price regu-
 4 lations may be remedied.

5 (7) In parallel trade regimes, how much of the
 6 price difference between countries in the European
 7 Union is captured by middlemen and how much goes
 8 to benefit patients and health systems where parallel
 9 importing is significant.

10 (8) How much cost is imposed on the owner of
 11 a property right from counterfeiting and from inter-
 12 national violations of intellectual property rights for
 13 prescription medicines.

14 (b) REPORT.—Not later than 1 year after the date
 15 of enactment of this Act, the Comptroller General of the
 16 United States shall submit to Congress a report on the
 17 study conducted under subsection (a).

18 **SEC. 635. SAFETY NET ORGANIZATIONS AND PATIENT ADVI-**
 19 **SORY COMMISSION.**

20 (a) IN GENERAL.—Title XI (42 U.S.C. 1320 et seq.)
 21 is amended by adding at the end the following new part:

1 “PART D—SAFETY NET ORGANIZATIONS AND PATIENT
2 *advisory* ADVISORY COMMISSION

3 “SAFETY NET ORGANIZATIONS AND PATIENT ADVISORY
4 COMMISSION

5 “SEC. 1181. (a) ESTABLISHMENT.—There is hereby
6 established the Safety Net Organizations and Patient Ad-
7 visory Commission (in this section referred to as the ‘Com-
8 mission’). *Encouraged to submit and*

9 “(b) REVIEW OF HEALTH CARE SAFETY NET PRO-
10 GRAMS AND REPORTING REQUIREMENTS.—

11 “(1) REVIEW.—The Commission shall conduct
12 an ongoing review of the health care safety net pro-
13 grams (as described in paragraph (3)(C)) by—

14 “(A) monitoring each health care safety
15 net program to document and analyze the ef-
16 fects of changes in these programs on the core
17 health care safety net;

18 “(B) evaluating the impact of the Emer-
19 gency Medical Treatment and Labor Act, the
20 Health Insurance Portability and Accountability
21 Act of 1996, the Balanced Budget Act of 1997,
22 the Medicare, Medicaid, and SCHIP Balanced
23 Budget Refinement Act of 1999, the Medicare,
24 Medicaid, and SCHIP Benefits Protection and
25 Improvement Act of 2000, Prescription Drug

1 and Medicare Improvement Act of 2003, and
2 other forces on the capacity of the core health
3 care safety net to continue their roles in the
4 core health care safety net system to care for
5 uninsured individuals, medicaid beneficiaries,
6 and other vulnerable populations;

7 “(C) monitoring existing data sets to as-
8 sess the status of the core health care safety
9 net and health outcomes for vulnerable popu-
10 lations;

11 “(D) wherever possible, linking and inte-
12 grating existing data systems to enhance the
13 reliability of the core health care safety net to
14 track changes in the status of the core health
15 care safety net and health outcomes for vulner-
16 able populations;

17 “(E) supporting the development of new
18 data systems where existing data are insuffi-
19 cient or inadequate;

20 “(F) developing criteria and indicators of
21 impending core health care safety net failure;

22 “(G) establishing an early-warning system
23 to identify impending failures of core health
24 care safety net systems and providers;

1 “(H) providing accurate and timely infor-
2 mation to Federal, State, and local policy-
3 makers on the indicators that may lead to the
4 failure of the core health care safety net and an
5 estimate of the projected consequences of such
6 failures and the impact of such a failure on the
7 community;

8 “(I) monitoring and providing oversight for
9 the transition of individuals receiving supple-
10 mental security income benefits, medical assist-
11 ance under title XIX, or child health assistance
12 under title XXI who enroll with a managed care
13 entity (as defined in section 1932(a)(1)(B)), in-
14 cluding the review of—

15 “(i) the degree to which health plans
16 have the capacity (including case manage-
17 ment and management information system
18 infrastructure) to provide quality managed
19 care services to such an individual;

20 “(ii) the degree to which these plans
21 may be overburdened by adverse selection;
22 and

23 “(iii) the degree to which emergency
24 departments are used by enrollees of these
25 plans; and

1 “(J) identifying and disseminating the best
2 practices for more effective application of the
3 lessons that have been learned.

4 “(2) REPORTS.—

5 “(A) ANNUAL REPORTS.—Not later than
6 June 1 of each year (beginning with 2005), the
7 Commission shall, based on the review con-
8 ducted under paragraph (1), submit to the ap-
9 propriate committees of Congress a report on—

10 “(i) the health care needs of the unin-
11 sured; and

12 “(ii) the financial and infrastructure
13 stability of the Nation’s core health care
14 safety net.

15 “(B) AGENDA AND ADDITIONAL RE-
16 VIEWS.—

17 “(i) AGENDA.—The Chair of the
18 Commission shall consult periodically with
19 the Chairpersons and Ranking Minority
20 Members of the appropriate committees of
21 Congress regarding the Commission’s
22 agenda and progress toward achieving the
23 agenda.

24 “(ii) ADDITIONAL REVIEWS.—The
25 Commission shall conduct additional re-

views and submit additional reports to the appropriate committees of Congress on topics relating to the health care safety net programs under the following circumstances:

“(I) If requested by the Chair-
persons or Ranking Minority Members
of such committees.

“(II) If the Commission deems
such additional reviews and reports
appropriate.

“(C) AVAILABILITY OF REPORTS.—The
Commission shall transmit to the Comptroller
General and the Secretary a copy of each report
submitted under this subsection and shall make
such reports available to the public.

“(3) DEFINITIONS.—In this section:

“(A) APPROPRIATE COMMITTEES OF CON-
GRESS.—The term ‘appropriate committees of
Congress’ means the Committees on Ways and
Means and Energy and Commerce of the House
of Representatives and the Committees on Fi-
nance and Health, Education, Labor, and Pen-
sions of the Senate.

1 “(B) CORE HEALTH CARE SAFETY NET.—

2 The term ‘core health care safety net’ means
3 any health care provider that—

4 “(i) by legal mandate or explicitly
5 adopted mission, offers access to health
6 care services to patients, regardless of the
7 ability of the patient to pay for such serv-
8 ices; and

9 “(ii) has a case mix that is substan-
10 tially comprised of patients who are unin-
11 sured, covered under the medicaid pro-
12 gram, covered under any other public
13 health care program, or are otherwise vul-
14 nerable populations.

15 Such term includes disproportionate share hos-
16 pitals, Federally qualified health centers, other
17 Federal, State, and locally supported clinics,
18 rural health clinics, local health departments,
19 and providers covered under the Emergency
20 Medical Treatment and Labor Act.

21 “(C) HEALTH CARE SAFETY NET PRO-
22 GRAMS.—The term ‘health care safety net pro-
23 grams’ includes the following:

24 “(i) MEDICAID.—The medicaid pro-
25 gram under title XIX.

1 “(ii) SCHIP.—The State children’s
2 health insurance program under title XXI.

3 “(iii) MATERNAL AND CHILD HEALTH
4 SERVICES BLOCK GRANT PROGRAM.—The
5 maternal and child health services block
6 grant program under title V.

7 “(iv) FQHC PROGRAMS.—Each feder-
8 ally funded program under which a health
9 center (as defined in section 330(1) of the
10 Public Health Service Act), a Federally
11 qualified health center (as defined in sec-
12 tion 1861(aa)(4)), or a Federally-qualified
13 health center (as defined in section
14 1905(l)(2)(B)) receives funds.

15 “(v) RHC PROGRAMS.—Each feder-
16 ally funded program under which a rural
17 health clinic (as defined in section
18 1861(aa)(4) or 1905(l)(1)) receives funds.

19 “(vi) DSH PAYMENT PROGRAMS.—
20 Each federally funded program under
21 which a disproportionate share hospital re-
22 ceives funds. 1905(l)(2)(B)”

23 “(vii) EMERGENCY MEDICAL TREAT-
24 MENT AND ACTIVE LABOR ACT.—All care
25 provided under section 1867 for the unin-

1 insured, underinsured, beneficiaries under
2 title XIX, and other vulnerable individuals.

3 “(viii) OTHER HEALTH CARE SAFETY
4 NET PROGRAMS.—Such term also includes
5 any other health care program that the
6 Commission determines to be appropriate.

7 “(D) VULNERABLE POPULATIONS.—The
8 term ‘vulnerable populations’ includes unin-
9 sured and underinsured individuals, low-income
10 individuals, farm workers, homeless individuals,
11 individuals with disabilities, individuals with
12 HIV or AIDS, and such other individuals as the
13 Commission may designate.

14 “(c) MEMBERSHIP.—

15 “(1) NUMBER AND APPOINTMENT.—The Com-
16 mission shall be composed of 13 members appointed
17 by the Comptroller General of the United States (in
18 this section referred to as the ‘Comptroller Gen-
19 eral’), in consultation with the appropriate commit-
20 tees of Congress.

21 “(2) QUALIFICATIONS.—

22 “(A) IN GENERAL.—The membership of
23 the Commission shall include individuals with
24 national recognition for their expertise in health
25 finance and economics, health care safety net

1 research and program management, actuarial
2 science, health facility management, health
3 plans and integrated delivery systems, reim-
4 bursement of health facilities, allopathic and os-
5 teopathic medicine (including emergency medi-
6 cine), and other providers of health services,
7 and other related fields, who provide a mix of
8 different professionals, broad geographic rep-
9 resentation, and a balance between urban and
10 rural representatives.

11 “(B) INCLUSION.—The membership of the
12 Commission shall include health professionals,
13 employers, third-party payers, individuals
14 skilled in the conduct and interpretation of bio-
15 medical, health services, and health economics
16 research and expertise in outcomes and effec-
17 tiveness research and technology assessment.
18 Such membership shall also include recipients
19 of care from core health care safety net and in-
20 dividuals who provide and manage the delivery
21 of care by the core health care safety net.

22 “(C) MAJORITY NONPROVIDERS.—Individ-
23 uals who are directly involved in the provision,
24 or management of the delivery, of items and
25 services covered under the health care safety

1 net programs shall not constitute a majority of
2 the membership of the Commission.

3 “(D) ETHICAL DISCLOSURE.—The Comp-
4 troller General shall establish a system for pub-
5 lic disclosure by members of the Commission of
6 financial and other potential conflicts of interest
7 relating to such members.

8 “(3) TERMS.—

9 “(A) IN GENERAL.—The terms of mem-
10 bers of the Commission shall be for 3 years ex-
11 cept that of the members first appointed, the
12 Comptroller General shall designate—

13 “(i) four to serve a term of 1 year;

14 “(ii) four to serve a term of 2 years;

15 and

16 “(iii) five to serve a term of 3 years.

17 “(B) VACANCIES.—

18 “(i) IN GENERAL.—A vacancy in the
19 Commission shall be filled in the same
20 manner in which the original appointment
21 was made.

22 “(ii) APPOINTMENT.—Any member
23 appointed to fill a vacancy occurring before
24 the expiration of the term for which the
25 member’s predecessor was appointed shall

be appointed only for the remainder of that term.

“(iii) TERMS.—A member may serve after the expiration of that member’s term until a successor has taken office.

“(4) COMPENSATION.—

“(A) MEMBERS.—While serving on the business of the Commission (including travel time), a member of the Commission—

“(i) shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code; and

“(ii) while so serving away from home and the member’s regular place of business, may be allowed travel expenses, as authorized by the Commission.

“(B) TREATMENT.—For purposes of pay (other than pay of members of the Commission) and employment benefits, rights, and privileges, all personnel of the Commission shall be treated as if they were employees of the United States Senate.

1 “(5) CHAIR; VICE CHAIR.—The Comptroller
2 General shall designate a member of the Commis-
3 sion, at the time of appointment of the member as
4 Chair and a member as Vice Chair for that term of
5 appointment, except that in the case of vacancy of
6 the Chair or Vice Chair, the Comptroller General
7 may designate another member for the remainder of
8 that member’s term.

9 “(6) MEETINGS.—The Commission shall meet
10 at the call of the Chair or upon the written request
11 of a majority of its members.

12 “(d) DIRECTOR AND STAFF; EXPERTS AND CON-
13 SULTANTS.—Subject to such review as the Comptroller
14 General determines necessary to ensure the efficient ad-
15 ministration of the Commission, the Commission may—

16 “(1) employ and fix the compensation of an Ex-
17 ecutive Director (subject to the approval of the
18 Comptroller General) and such other personnel as
19 may be necessary to carry out the duties of the
20 Commission under this section (without regard to
21 the provisions of title 5, United States Code, gov-
22 erning appointments in the competitive service);

23 “(2) seek such assistance and support as may
24 be required in the performance of the duties of the

Commission under this section from appropriate
Federal departments and agencies;

“(3) enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Commission (without regard to section 3709 of the Revised Statutes (41 U.S.C. 5));

“(4) make advance, progress, and other payments which relate to the work of the Commission;

“(5) provide transportation and subsistence for persons serving without compensation; and

“(6) prescribe such rules and regulations as it deems necessary with respect to the internal organization and operation of the Commission.

“(e) POWERS.—

“(1) OBTAINING OFFICIAL DATA.—

“(A) IN GENERAL.—The Commission may secure directly from any department or agency of the United States information necessary for the Commission to carry the duties under this section.

“(B) REQUEST OF CHAIR.—Upon request of the Chair, the head of that department or agency shall furnish that information to the Commission on an agreed upon schedule.

1 “(2) DATA COLLECTION.—In order to carry out
2 the duties of the Commission under this section, the
3 Commission shall—

4 “(A) use existing information, both pub-
5 lished and unpublished, where possible, collected
6 and assessed either by the staff of the Commis-
7 sion or under other arrangements made in ac-
8 cordance with this section;

9 “(B) carry out, or award grants or con-
10 tracts for, original research and experimen-
11 tation, where existing information is inad-
12 equate; and

13 “(C) adopt procedures allowing any inter-
14 ested party to submit information for the Com-
15 mission’s use in making reports and rec-
16 ommendations.

17 “(3) ACCESS OF GAO TO INFORMATION.—The
18 Comptroller General shall have unrestricted access
19 to all deliberations, records, and nonproprietary data
20 that pertains to the work of the Commission, imme-
21 diately upon request. The expense of providing such
22 information shall be borne by the General Account-
23 ing Office.

“(4) PERIODIC AUDIT.—The Commission shall be subject to periodic audit by the Comptroller General.

“(f) APPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) does not apply to the Commission.

“(g) AUTHORIZATION OF APPROPRIATIONS.—

“(1) REQUEST FOR APPROPRIATIONS.—The Commission shall submit requests for appropriations in the same manner as the Comptroller General submits requests for appropriations, but amounts appropriated for the Commission shall be separate from amounts appropriated for the Comptroller General.

“(2) AUTHORIZATION.—There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section.”.

(b) EFFECTIVE DATE.—The Comptroller General of the United States shall appoint the initial members of the Safety Net Organizations and Patient Advisory Commission established under subsection (a) not later than June 1, 2004.

SEC. 636. ESTABLISHMENT OF PROGRAM TO PREVENT

ABUSE OF NURSING FACILITY RESIDENTS.

(a) IN GENERAL.—

1 ~~insert~~ (1) SCREENING OF SKILLED NURSING FACILITY
 2 AND NURSING FACILITY PROVISIONAL EMPLOY-
 3 EES.—

4 (A) MEDICARE PROGRAM.—Section
 5 1819(b) (42 U.S.C. 1395i-3(b)) is amended by
 6 adding at the end the following:

7 “(8) SCREENING OF SKILLED NURSING FACIL-
 8 ITY WORKERS.—

9 “(A) BACKGROUND CHECKS OF PROVI-
 10 SIONAL EMPLOYEES.—Subject to subparagraph
 11 (B)(ii), after a skilled nursing facility selects an
 12 individual for a position as a skilled nursing fa-
 13 cility worker, the facility, prior to employing
 14 such worker in a status other than a provisional
 15 status to the extent permitted under subpara-
 16 graph (B)(ii), shall—

17 “(i) give such worker written notice
 18 that the facility is required to perform
 19 background checks with respect to provi-
 20 sional employees;

21 “(ii) require, as a condition of employ-
 22 ment, that such worker—

23 ~~insert~~ “(I) provide a written statement
 24 ~~insert~~ disclosing any conviction for a rel-

1 have no relevant crime or finding of patient or
2 sexual or resident abuse;

3 (ii)“(II) provide a statement signed
4 by the worker authorizing the facility
5 to request the search and exchange of
6 criminal records;

7 (iii)“(III) provide in person to the
8 facility a copy of the worker’s finger-
9 prints or thumb print, depending
10 upon available technology; and

11 (iv)“(IV) provide any other identi-
12 fication information the Secretary
13 may specify in regulation;

14 “(iii) initiate a check of the data col-
15 lection system established under section
16 1128E in accordance with regulations pro-
17 mulgated by the Secretary to determine
18 whether such system contains any disquali-
19 fying information with respect to such
20 worker; and

21 “(iv)“(iv) if that system does not contain
22 any such disqualifying information—

23 “(i)“(I) request through the appro-
24 priate State agency that the State ini-
25 tiate a State and national criminal

1 background check on such worker in

2 accordance with the provisions of sub-

3 section (e)(6); and

4 “(II) submit to such State agen-

5 cy the information described in sub-

6 clauses (II) through (IV) of clause (ii)

7 not more than 7 days (excluding Sat-

8 urdays, Sundays, and legal public

9 holidays under section 6103(a) of title

10 5, United States Code) after comple-

11 tion of the check against the system

12 initiated under clause (iii).

13 “(B) PROHIBITION ON HIRING OF ABUSIVE

14 WORKERS.—

15 “(i) IN GENERAL.—A skilled nursing

16 facility may not knowingly employ any

17 skilled nursing facility worker who has any

18 conviction for a relevant crime or with re-

19 spect to whom a finding of patient or resi-

20 dent abuse has been made.

21 “(ii) PROVISIONAL EMPLOYMENT.—

22 After complying with the requirements of

23 clauses (i), (ii), and (iii) of subparagraph

24 (A), a skilled nursing facility may provide

25 for a provisional period of employment for

a skilled nursing facility worker pending
 completion of the check against the data
 collection system described under subpara-
 graph (A)(iii) and the background check
 described under subparagraph (A)(iv).

Subject to clause (iii), such facility shall
 maintain direct supervision of the covered
 individual during the worker's provisional
 period of employment.

“(iii) EXCEPTION FOR SMALL RURAL

SKILLED NURSING FACILITIES.—In the
 case of a small rural skilled nursing facility
 (as defined by the Secretary), the Sec-
 retary shall provide, by regulation after
 consultation with providers of skilled nurs-
 ing facility services and entities rep-
 resenting beneficiaries of such services, for
 an appropriate level of supervision with re-
 spect to any provisional employees em-
 ployed by the facility in accordance with
 clause (ii). Such regulation should encour-
 age the provision of direct supervision of
 such employees whenever practicable with
 respect to such a facility and if such super-

vision would not impose an unreasonable cost or other burden on the facility.

“(C) REPORTING REQUIREMENTS.—A skilled nursing facility shall report to the State any instance in which the facility determines that a skilled nursing facility worker has committed an act of resident neglect or abuse or misappropriation of resident property in the course of employment by the facility.

“(D) USE OF INFORMATION.—

“(i) IN GENERAL.—A skilled nursing facility that obtains information about a skilled nursing facility worker pursuant to clauses (iii) and (iv) of subparagraph (A) may use such information only for the purpose of determining the suitability of the worker for employment.

“(ii) IMMUNITY FROM LIABILITY.—A skilled nursing facility that, in denying employment for an individual selected for hiring as a skilled nursing facility worker (including during the period described in subparagraph (B)(ii)), reasonably relies upon information about such individual provided by the State pursuant to subsection (e)(6)

section 1128E shall not be liable in any action brought by such individual based on the employment determination resulting from the information.

“(iii) CRIMINAL PENALTY.—Whoever knowingly violates the provisions of clause (i) shall be fined in accordance with title 18, United States Code, imprisoned for not more than 2 years, or both.

“(E) CIVIL PENALTY.—

“(i) IN GENERAL.—A skilled nursing facility that violates the provisions of this paragraph shall be subject to a civil penalty in an amount not to exceed—

“(I) for the first such violation, \$2,000; and
“(II) for the second and each subsequent violation within any 5-year period, \$5,000.

“(ii) KNOWING RETENTION OF WORKER.—In addition to any civil penalty under clause (i), a skilled nursing facility that—
“(I) knowingly continues to employ a skilled nursing facility worker

1 in violation of subparagraph (A) or
2 (B); or

3 “(II) knowingly fails to report a
4 skilled nursing facility worker under
5 subparagraph (C),

6 shall be subject to a civil penalty in an
7 amount not to exceed \$5,000 for the first
8 such violation, and \$10,000 for the second
9 and each subsequent violation within any
10 5-year period.

11 “(F) DEFINITIONS.—In this paragraph:

12 “(i) CONVICTION FOR A RELEVANT
13 CRIME.—The term ‘conviction for a rel-
14 evant crime’ means any Federal or State
15 criminal conviction for—

16 “(I) any offense described in
17 paragraphs (1) through (4) of section
18 1128(a); and

19 “(II) such other types of offenses
20 as the Secretary may specify in regu-
21 lations, taking into account the sever-
22 ity and relevance of such offenses, and
23 after consultation with representatives
24 of long-term care providers, represent-
25 atives of long-term care employees,

consumer advocates, and appropriate
Federal and State officials.

“(ii) DISQUALIFYING INFORMATION.—

The term ‘disqualifying information’ means
information about a conviction for a rel-
evant crime or a finding of patient or resi-
dent abuse.

“(iii) FINDING OF PATIENT OR RESI-
DENT ABUSE.—The term ‘finding of pa-
tient or resident abuse’ means any sub-
stantiated finding by a State agency under
subsection (g)(1)(C) or a Federal agency
that a skilled nursing facility worker has
committed—

“(I) an act of patient or resident
abuse or neglect or a misappropriation
of patient or resident property; or

“(II) such other types of acts as
the Secretary may specify in regula-
tions.

“(iv) SKILLED NURSING FACILITY
WORKER.—The term ‘skilled nursing facil-
ity worker’ means any individual (other
than a volunteer) that has access to a pa-
tient of a skilled nursing facility under an

employment or other contract, or both, with such facility. Such term includes individuals who are licensed or certified by the State to provide such services, and non-licensed individuals providing such services, as defined by the Secretary, including nurse assistants, nurse aides, home health aides, and personal care workers and attendants.”.

(B) MEDICAID PROGRAM.—Section 1919(b) (42 U.S.C. 1396r(b)) is amended by adding at the end the following new paragraph:

“(8) SCREENING OF NURSING FACILITY WORK-

ERS.—

“(A) BACKGROUND CHECKS ON PROVISIONAL EMPLOYEES.—Subject to subparagraph (B)(ii), after a nursing facility selects an individual for a position as a nursing facility worker, the facility, prior to employing such worker in a status other than a provisional status to the extent permitted under subparagraph (B)(ii), shall—

“(i) give the worker written notice that the facility is required to perform

background checks with respect to provisional employees;

“(ii) require, as a condition of employment, that such worker—

“(I) provide a written statement disclosing any conviction for a relevant crime or finding of patient or resident abuse;

“(II) provide a statement signed by the worker authorizing the facility to request the search and exchange of criminal records;

“(III) provide in person to the facility a copy of the worker’s fingerprints or thumb print, depending upon available technology; and

“(IV) provide any other identification information the Secretary may specify in regulation;

“(iii) initiate a check of the data collection system established under section 1128E in accordance with regulations promulgated by the Secretary to determine whether such system contains any disquali-

1 fying information with respect to such
2 worker; and

3 “(iv) if that system does not contain
4 any such disqualifying information—

5 “(I) request through the appro-
6 priate State agency that the State ini-
7 tiate a State and national criminal
8 background check on such worker in
9 accordance with the provisions of sub-
10 section (e)(8); and

11 “(II) submit to such State agen-
12 cy the information described in sub-
13 clauses (II) through (IV) of clause (ii)
14 not more than 7 days (excluding Sat-
15 urdays, Sundays, and legal public
16 holidays under section 6103(a) of title
17 5, United States Code) after comple-
18 tion of the check against the system
19 initiated under clause (iii).

20 “(B) PROHIBITION ON HIRING OF ABUSIVE
21 WORKERS.—

22 “(i) IN GENERAL.—A nursing facility
23 may not knowingly employ any nursing fa-
24 cility worker who has any conviction for a
25 relevant crime or with respect to whom a

1 detection of patient or resident abuse has
2 been made.

3 “(ii) PROVISIONAL EMPLOYMENT.—

4 After complying with the requirements of
5 subclauses (i), (ii), and (iii) of subparagraph

6 (A), a nursing facility may provide for a
7 provisional period of employment for a

8 nursing facility worker pending completion
9 of the check against the data collection

10 system described under subparagraph

11 (A)(iii) and the background check de-

12 scribed under subparagraph (A)(iv). Sub-

13 ject to clause (iii), such facility shall main-

14 tain direct supervision of the worker dur-

15 ing the worker's provisional period of em-

16 ployment.

17 “(iii) EXCEPTION FOR SMALL RURAL

18 NURSING FACILITIES.—

19 “(I) IN GENERAL.—In the case

20 of a small rural nursing facility (as

21 defined by the Secretary), the Sec-

22 retary shall provide, by regulation

23 after consultation with providers of

24 nursing facility services and entities

25 representing beneficiaries of such

1 services, for an appropriate level of
2 supervision with respect to any provi-
3 sional employees employed by the fa-
4 cility in accordance with clause (ii).
5 Such regulation should encourage the
6 provision of direct supervision of such
7 employees whenever practicable with
8 respect to such a facility and if such
9 supervision would not impose an un-
10 reasonable cost or other burden on the
11 facility.

12 “(C) REPORTING REQUIREMENTS.—A
13 nursing facility shall report to the State any in-
14 stance in which the facility determines that a
15 nursing facility worker has committed an act of
16 resident neglect or abuse or misappropriation of
17 resident property in the course of employment
18 by the facility.

19 “(D) USE OF INFORMATION.—

20 “(i) IN GENERAL.—A nursing facility
21 that obtains information about a nursing
22 facility worker pursuant to clauses (iii) and
23 (iv) of subparagraph (A) may use such in-
24 formation only for the purpose of deter-

termining the suitability of the worker for
employment.

“(ii) IMMUNITY FROM LIABILITY.—A
nursing facility that, in denying employ-
ment for an individual selected for hiring
as a nursing facility worker (including dur-
ing the period described in subparagraph
(B)(ii)), reasonably relies upon information
about such individual provided by the
State pursuant to subsection (e)(6) or sec-
tion 1128E shall not be liable in any ac-
tion brought by such individual based on
the employment determination resulting
from the information.

“(iii) CRIMINAL PENALTY.—Whoever
knowingly violates the provisions of clause
(i) shall be fined in accordance with title
18, United States Code, imprisoned for not
more than 2 years, or both.

“(E) CIVIL PENALTY.—

“(i) IN GENERAL.—A nursing facility
that violates the provisions of this para-
graph shall be subject to a civil penalty in
an amount not to exceed—

1 “(I) for the first such violation,
2 \$2,000; and

3 “(II) for the second and each
4 subsequent violation within any 5-year
5 period, \$5,000.

6 “(ii) KNOWING RETENTION OF WORK-
7 ER.—In addition to any civil penalty under
8 clause (i), a nursing facility that—

9 “(I) knowingly continues to em-
10 ploy a nursing facility worker in viola-
11 tion of subparagraph (A) or (B); or

12 “(II) knowingly fails to report a
13 nursing facility worker under subpara-
14 graph (C),

15 shall be subject to a civil penalty in an
16 amount not to exceed \$5,000 for the first
17 such violation, and \$10,000 for the second
18 and each subsequent violation within any
19 5-year period.

20 “(F) DEFINITIONS.—In this paragraph:

21 “(i) CONVICTION FOR A RELEVANT
22 CRIME.—The term ‘conviction for a rel-
23 evant crime’ means any Federal or State
24 criminal conviction for—

“(I) any offense described in paragraphs (1) through (4) of section 1128(a); and

“(II) such other types of offenses as the Secretary may specify in regulations, taking into account the severity and relevance of such offenses, and after consultation with representatives of long-term care providers, representatives of long-term care employees, consumer advocates, and appropriate Federal and State officials.

“(ii) DISQUALIFYING INFORMATION.—

The term ‘disqualifying information’ means information about a conviction for a relevant crime or a finding of patient or resident abuse.

“(iii) FINDING OF PATIENT OR RESIDENT ABUSE.—

The term ‘finding of patient or resident abuse’ means any substantiated finding by a State agency under subsection (g)(1)(C) or a Federal agency that a nursing facility worker has committed—

1 “(I) an act of patient or resident
2 abuse or neglect or a misappropriation
3 of patient or resident property; or

4 “(II) such other types of acts as
5 the Secretary may specify in regula-
6 tions.

7 “(iv) NURSING FACILITY WORKER.—

8 The term ‘nursing facility worker’ means
9 any individual (other than a volunteer)
10 that has access to a patient of a nursing
11 facility under an employment or other con-
12 tract, or both, with such facility. Such
13 term includes individuals who are licensed
14 or certified by the State to provide such
15 services, and nonlicensed individuals pro-
16 viding such services, as defined by the Sec-
17 retary, including nurse assistants, nurse
18 aides, home health aides, and personal care
19 workers and attendants.”.

20 (2) FEDERAL RESPONSIBILITIES.—

21 (A) DEVELOPMENT OF STANDARD FED-
22 ERAL AND STATE BACKGROUND CHECK
23 FORM.—The Secretary of Health and Human
24 Services, in consultation with the Attorney Gen-
25 eral and representatives of appropriate State

1 agencies, shall develop a model form that a pro-
2 visional employee at a nursing facility may com-
3 plete and Federal and State agencies may use
4 to conduct the criminal background checks re-
5 quired under sections 1819(b)(8) and
6 1919(b)(8) of the Social Security Act (42
7 U.S.C. 1395i-3(b), 1396r(b)) (as added by this
8 section).

9 (B) PERIODIC EVALUATION.—The Sec-
10 retary of Health and Human Services, in con-
11 sultation with the Attorney General, periodically
12 shall evaluate the background check system im-
13 posed under sections 1819(b)(8) and
14 1919(b)(8) of the Social Security Act (42
15 U.S.C. 1395i-3(b), 1396r(b)) (as added by this
16 section) and shall implement changes, as nec-
17 essary, based on available technology, to make
18 the background check system more efficient and
19 able to provide a more immediate response to
20 long-term care providers using the system.

21 (3) NO PREEMPTION OF STRICTER STATE
22 LAWS.—Nothing in section 1819(b)(8) or 1919(b)(8)
23 of the Social Security Act (42 U.S.C. 1395i-3(b)(8),
24 1396r(b)(8)) (as so added) shall be construed to su-
25 persede any provision of State law that—

1 (A) specifies a relevant crime for purposes
 2 of prohibiting the employment of an individual
 3 at a long-term care facility (as defined in sec-
 4 tion 1128E(g)(6) of the Social Security Act (as
 5 added by subsection (e)) that is not included in
 6 the list of such crimes specified in such sections
 7 or in regulations promulgated by the Secretary
 8 of Health and Human Services to carry out
 9 such sections; or

10 (B) requires a long-term care facility (as
 11 so defined) to conduct a background check prior
 12 to employing an individual in an employment
 13 position that is not included in the positions for
 14 which a background check is required under
 15 such sections.

16 (4) TECHNICAL AMENDMENTS.—Effective as if
 17 included in the enactment of section 941 of BIPA
 18 (114 Stat. 2763A–585), sections 1819(b) and
 19 1919(b) (42 U.S.C. 1395i–3(b), 1396r(b)), as
 20 amended by such section 941 are each amended by
 21 redesignating the paragraph (8) added by such sec-
 22 tion as paragraph (9).

23 (b) FEDERAL AND STATE REQUIREMENTS CON-
 24 CERNING BACKGROUND CHECKS.—

(1) MEDICARE.—Section 1819(e) (42 U.S.C. 1395i-3(e)) is amended by adding at the end the following:

“(6) FEDERAL AND STATE REQUIREMENTS CONCERNING CRIMINAL BACKGROUND CHECKS ON SKILLED NURSING FACILITY EMPLOYEES.—

“(A) IN GENERAL.—Upon receipt of a request by a skilled nursing facility pursuant to subsection (b)(8) that is accompanied by the information described in subclauses (II) through (IV) of subsection (b)(8)(A)(ii), a State, after checking appropriate State records and finding no disqualifying information (as defined in subsection (b)(8)(F)(ii)), shall immediately submit such request and information to the Attorney General and shall request the Attorney General to conduct a search and exchange of records with respect to the individual as described in subparagraph (B).

“(B) SEARCH AND EXCHANGE OF RECORDS BY ATTORNEY GENERAL.—Upon receipt of a submission pursuant to subparagraph (A), the Attorney General shall direct a search of the records of the Federal Bureau of Investigation for any criminal history records cor-

1 responding to the fingerprints and other posi-
 2 tive identification information submitted. The
 3 Attorney General shall provide any cor-
 4 responding information resulting from the
 5 search to the State.

6 “(C) STATE REPORTING OF INFORMATION
 7 TO SKILLED NURSING FACILITY.—Upon receipt
 8 of the information provided by the Attorney
 9 General pursuant to subparagraph (B), the
 10 State shall—

11 “(i) review the information to deter-
 12 mine whether the individual has any con-
 13 viction for a relevant crime (as defined in
 14 subsection (b)(8)(F)(i));

15 “(ii) immediately report to the skilled
 16 nursing facility in writing the results of
 17 such review; and

18 “(iii) in the case of an individual with
 19 a conviction for a relevant crime, report
 20 the existence of such conviction of such in-
 21 dividual to the database established under
 22 section 1128E.

23 “(D) FEES FOR PERFORMANCE OF CRIMI-
 24 NAL BACKGROUND CHECKS.—

25 “(i) AUTHORITY TO CHARGE FEES.—

“(I) ATTORNEY GENERAL.—The Attorney General may charge a fee to any State requesting a search and exchange of records pursuant to this paragraph and subsection (b)(8) for conducting the search and providing the records. The amount of such fee shall not exceed the lesser of the actual cost of such activities or \$50. Such fees shall be available to the Attorney General, or, in the Attorney General’s discretion, to the Federal Bureau of Investigation until expended.

“(II) STATE.—A State may charge a skilled nursing facility a fee for initiating the criminal background check under this paragraph and subsection (b)(8), including fees charged by the Attorney General, and for performing the review and report required by subparagraph (C). The amount of such fee shall not exceed the actual cost of such activities.

1 “(ii) PROHIBITION ON CHARGING.—

2 An entity may not impose on a provisional
3 employee or an employee any charges re-
4 lating to the performance of a background
5 check under this paragraph.

6 “(E) REGULATIONS.—

7 “(i) IN GENERAL.—In addition to the
8 Secretary’s authority to promulgate regula-
9 tions under this title, the Attorney Gen-
10 eral, in consultation with the Secretary,
11 may promulgate such regulations as are
12 necessary to carry out the Attorney Gen-
13 eral’s responsibilities under this paragraph
14 and subsection (b)(9), including regula-
15 tions regarding the security confidentiality,
16 accuracy, use, destruction, and dissemina-
17 tion of information, audits and record-
18 keeping, and the imposition of fees.

19 “(ii) APPEAL PROCEDURES.—The At-
20 torney General, in consultation with the
21 Secretary, shall promulgate such regula-
22 tions as are necessary to establish proce-
23 dures by which a provisional employee or
24 an employee may appeal or dispute the ac-
25 curacy of the information obtained in a

background check conducted under this paragraph. Appeals shall be limited to instances in which a provisional employee or an employee is incorrectly identified as the subject of the background check, or when information about the provisional employee or an employee has not been updated to reflect changes in the provisional employee's or an employee's criminal record.

“(F) REPORT.—Not later than 2 years after the date of enactment of this paragraph, the Attorney General shall submit a report to Congress on—

- “(i) the number of requests for searches and exchanges of records made under this section;
- “(ii) the disposition of such requests; and
- “(iii) the cost of responding to such requests.”.

(2) MEDICAID.—Section 1919(e) (42 U.S.C. 1396r(e)) is amended by adding at the end the following:

1 “(8) FEDERAL AND STATE REQUIREMENTS
2 CONCERNING CRIMINAL BACKGROUND CHECKS ON
3 NURSING FACILITY EMPLOYEES.—

4 “(A) IN GENERAL.—Upon receipt of a re-
5 quest by a nursing facility pursuant to sub-
6 section (b)(8) that is accompanied by the infor-
7 mation described in subclauses (II) through
8 (IV) of subsection (b)(8)(A)(ii), a State, after
9 checking appropriate State records and finding
10 no disqualifying information (as defined in sub-
11 section (b)(8)(F)(ii)), shall immediately submit
12 such request and information to the Attorney
13 General and shall request the Attorney General
14 to conduct a search and exchange of records
15 with respect to the individual as described in
16 subparagraph (B).

17 “(B) SEARCH AND EXCHANGE OF
18 RECORDS BY ATTORNEY GENERAL.—Upon re-
19 ceipt of a submission pursuant to subparagraph
20 (A), the Attorney General shall direct a search
21 of the records of the Federal Bureau of Inves-
22 tigation for any criminal history records cor-
23 responding to the fingerprints and other posi-
24 tive identification information submitted. The
25 Attorney General shall provide any cor-

1 responding information resulting from the
2 search to the State.

3 “(C) STATE REPORTING OF INFORMATION
4 TO NURSING FACILITY.—Upon receipt of the in-
5 formation provided by the Attorney General
6 pursuant to subparagraph (B), the State
7 shall—

8 “(i) review the information to deter-
9 mine whether the individual has any con-
10 viction for a relevant crime (as defined in
11 subsection (b)(8)(F)(i));

12 “(ii) immediately report to the nurs-
13 ing facility in writing the results of such
14 review; and

15 “(iii) in the case of an individual with
16 a conviction for a relevant crime, report
17 the existence of such conviction of such in-
18 dividual to the database established under
19 section 1128E.

20 “(D) FEES FOR PERFORMANCE OF CRIMI-
21 NAL BACKGROUND CHECKS.—

22 “(i) AUTHORITY TO CHARGE FEES.—

23 “(I) ATTORNEY GENERAL.—The
24 Attorney General may charge a fee to
25 any State requesting a search and ex-

1 change of records pursuant to this
 2 paragraph and subsection (b)(8) for
 3 conducting the search and providing
 4 the records. The amount of such fee
 5 shall not exceed the lesser of the ac-
 6 tual cost of such activities or \$50.
 7 Such fees shall be available to the At-
 8 torney General, or, in the Attorney
 9 General's discretion, to the Federal
 10 Bureau of Investigation, until ex-
 11 pended.

12 *100-100-100-100*“(II) STATE.—A State may
 13 charge a nursing facility a fee for ini-
 14 tiating the criminal background check
 15 *100-100-100-100* under this paragraph and subsection
 16 (b)(8), including fees charged by the
 17 Attorney General, and for performing
 18 the review and report required by sub-
 19 paragraph (C). The amount of such
 20 fee shall not exceed the actual cost of
 21 such activities.

22 “(ii) PROHIBITION ON CHARGING.—
 23 An entity may not impose on a provisional
 24 *100-100-100-100* employee or an employee any charges re-

1 lating to the performance of a background
2 check under this paragraph.

3 “(E) REGULATIONS.—

4 “(i) IN GENERAL.—In addition to the
5 Secretary’s authority to promulgate regula-
6 tions under this title, the Attorney Gen-
7 eral, in consultation with the Secretary,
8 may promulgate such regulations as are
9 necessary to carry out the Attorney Gen-
10 eral’s responsibilities under this paragraph
11 and subsection (b)(8), including regula-
12 tions regarding the security, confiden-
13 tiality, accuracy, use, destruction, and dis-
14 semination of information, audits and rec-
15 ordkeeping, and the imposition of fees.

16 “(ii) APPEAL PROCEDURES.—The At-
17 torney General, in consultation with the
18 Secretary, shall promulgate such regula-
19 tions as are necessary to establish proce-
20 dures by which a provisional employee or
21 an employee may appeal or dispute the ac-
22 curacy of the information obtained in a
23 background check conducted under this
24 paragraph. Appeals shall be limited to in-
25 stances in which a provisional employee or

1 an employee is incorrectly identified as the
2 subject of the background check, or when
3 information about the provisional employee
4 or employee has not been updated to re-
5 flect changes in the provisional employee's
6 or employee's criminal record.

7 “(F) REPORT.—Not later than 2 years
8 after the date of enactment of this paragraph,
9 the Attorney General shall submit a report to
10 Congress on—

11 “(i) the number of requests for
12 searches and exchanges of records made
13 under this section;

14 “(ii) the disposition of such requests;
15 and

16 “(iii) the cost of responding to such
17 requests.”.

18 (c) APPLICATION TO OTHER ENTITIES PROVIDING
19 HOME HEALTH OR LONG-TERM CARE SERVICES.—

20 (1) MEDICARE.—Part D of title XVIII (42
21 U.S.C. 1395x et seq.) is amended by adding at the
22 end the following:

1 “APPLICATION OF SKILLED NURSING FACILITY PREVEN-
2 TIVE ABUSE PROVISIONS TO ANY PROVIDER OF
3 SERVICES OR OTHER ENTITY PROVIDING HOME
4 HEALTH OR LONG-TERM CARE SERVICES

5 “SEC. 1897. (a) IN GENERAL.—The requirements of
6 subsections (b)(8) and (e)(6) of section 1819 shall apply
7 to any provider of services or any other entity that is eligi-
8 ble to be paid under this title for providing home health
9 services, hospice care (including routine home care and
10 other services included in hospice care under this title),
11 or long-term care services to an individual entitled to bene-
12 fits under part A or enrolled under part B, including an
13 individual provided with a Medicare+Choice plan offered
14 by a Medicare+Choice organization under part C (in this
15 section referred to as a ‘medicare beneficiary’).

16 “(b) SUPERVISION OF PROVISIONAL EMPLOYEES.—

17 “(1) IN GENERAL.—With respect to an entity
18 that provides home health services, such entity shall
19 be considered to have satisfied the requirements of
20 section 1819(b)(8)(B)(ii) or 1919(b)(8)(B)(ii) if the
21 entity meets such requirements for supervision of
22 provisional employees of the entity as the Secretary
23 shall, by regulation, specify in accordance with para-
24 graph (2). *informed consultation* AS

1 “(2) REQUIREMENTS.—The regulations re-
2 quired under paragraph (1) shall provide the fol-
3 lowing:

4 “(A) Supervision of a provisional employee
5 shall consist of ongoing, good faith, verifiable
6 efforts by the supervisor of the provisional em-
7 ployee to conduct monitoring and oversight ac-
8 tivities to ensure the safety of a medicare bene-
9 ficiary.

10 “(B) For purposes of subparagraph (A),
11 monitoring and oversight activities may include
12 (but are not limited to) the following:

13 “(i) Follow-up telephone calls to the
14 medicare beneficiary.

15 “(ii) Unannounced visits to the medi-
16 care beneficiary’s home while the provi-
17 sional employee is serving the medicare
18 beneficiary.

19 “(iii) To the extent practicable, lim-
20 iting the provisional employee’s duties to
21 serving only those medicare beneficiaries in
22 a home or setting where another family
23 member or resident of the home or setting
24 of the medicare beneficiary is present.

“(C) In promulgating such regulations, the Secretary shall take into account the staffing and geographic issues faced by small rural entities (as defined by the Secretary) that provide home health services, hospice care (including routine home care and other services included in hospice care under this title), or other long-term care services. Such regulations should encourage the provision of monitoring and oversight activities whenever practicable with respect to such an entity, and if such activities would not impose an unreasonable cost or other burden on the entity.”.

(2) MEDICAID.—Section 1902(a) (42 U.S.C. 1396a), as amended by section 104(a), is amended—

(A) in paragraph (65), by striking “and” at the end;

(B) in paragraph (66), by striking the period and inserting “; and”; and

(C) by inserting after paragraph (66) the following:

“(67) provide that any entity that is eligible to be paid under the State plan for providing home health services, hospice care (including routine home

1 care and other services included in hospice care
 2 under title XVIII), or long-term care services for
 3 which medical assistance is available under the State
 4 plan to individuals requiring long-term care complies
 5 with the requirements of subsections (b)(8) and
 6 (e)(8) of section 1919 and section 1897(b) (in the
 7 same manner as such section applies to a medicare
 8 beneficiary).”.

9 (3) EXPANSION OF STATE NURSE AIDE REG-
 10 ISTRY.—

11 (A) MEDICARE.—Section 1819 (42 U.S.C.
 12 1395i-3) is amended—

13 (i) in subsection (e)(2)—

14 (I) in the paragraph heading, by
 15 striking “NURSE AIDE REGISTRY” and
 16 inserting “EMPLOYEE REGISTRY”;

17 (II) in subparagraph (A)—

18 (aa) by striking “By not
 19 later than January 1, 1989, the”
 20 and inserting “The”;

21 (bb) by striking “a registry
 22 of all individuals” and inserting
 23 “a registry of (i) all individuals”;

24 and

(cc) by inserting before the
 period the following: “, (ii) all
 other skilled nursing facility em-
 ployees with respect to whom the
 State has made a finding de-
 scribed in subparagraph (B), and
 (iii) any employee of any provider
 of services or any other entity
 that is eligible to be paid under
 this title for providing home
 health services, hospice care (in-
 cluding routine home care and
 other services included in hospice
 care under this title), or long-
 term care services and with re-
 spect to whom the entity has re-
 ported to the State a finding of
 patient neglect or abuse or a mis-
 appropriation of patient prop-
 erty”; and

(III) in subparagraph (C), by
 striking “a nurse aide” and inserting
 “an individual”; and

(ii) in subsection (g)(1)—

- 1 (i) of (I) by striking the first sentence
- 2 of subparagraph (C) and inserting the
- 3 following: "The State shall provide,
- 4 through the agency responsible for
- 5 surveys and certification of skilled
- 6 nursing facilities under this sub-
- 7 section, for a process for the receipt
- 8 and timely review and investigation of
- 9 allegations of neglect and abuse and
- 10 misappropriation of resident property
- 11 by a nurse aide or a skilled nursing
- 12 facility employee of a resident in a
- 13 skilled nursing facility, by another in-
- 14 dividual used by the facility in pro-
- 15 viding services to such a resident, or
- 16 by an individual described in sub-
- 17 section (e)(2)(A)(iii)."; and
- 18 (II) in the fourth sentence of
- 19 subparagraph (C), by inserting "or
- 20 described in subsection (e)(2)(A)(iii)"
- 21 after "used by the facility"; and
- 22 (III) in subparagraph (D)—
- 23 (aa) in the subparagraph
- 24 heading, by striking "NURSE
- 25 AIDE"; and

(bb) in clause (i), in the matter preceding subclause (I), by striking “a nurse aide” and inserting “an individual”; and

(cc) in clause (i)(I), by striking “nurse aide” and inserting “individual”.

(B) MEDICAID.—Section 1919 (42 U.S.C. 1396r) is amended—

(i) in subsection (e)(2)—

by striking (I) in the paragraph heading, by striking “NURSE AIDE REGISTRY” and inserting “EMPLOYEE REGISTRY”; and by striking (II) in subparagraph (A)—

(aa) by striking “By not later than January 1, 1989, the” and inserting “The”;

(bb) by striking “a registry of all individuals” and inserting “a registry of (i) all individuals”;

and

(cc) by inserting before the period the following: “, (ii) all other nursing facility employees with respect to whom the State

- 1 has made a finding described in
2 subparagraph (B), and (iii) any
3 employee of an entity that is eli-
4 gible to be paid under the State
5 plan for providing home health
6 services, hospice care (including
7 routine home care and other
8 services included in hospice care
9 under title XVIII), or long-term
10 care services and with respect to
11 whom the entity has reported to
12 the State a finding of patient ne-
13 glect or abuse or a misappropria-
14 tion of patient property”; and
15 (III) in subparagraph (C), by
16 striking “a nurse aide” and inserting
17 “an individual”; and
18 (ii) in subsection (g)(1)—
19 (I) by striking the first sentence
20 of subparagraph (C) and inserting the
21 following: “The State shall provide,
22 through the agency responsible for
23 surveys and certification of nursing
24 facilities under this subsection, for a
25 process for the receipt and timely re-

review and investigation of allegations
 of neglect and abuse and misappropriation of resident property by a
 nurse aide or a nursing facility employee of a resident in a nursing facility,
 by another individual used by the facility in providing services to such a
 resident, or by an individual described
 in subsection (e)(2)(A)(iii).”; and
 (II) in the fourth sentence of
 subparagraph (C), by inserting “or
 described in subsection (e)(2)(A)(iii)”
 after “used by the facility”; and
 (III) in subparagraph (D)—
 (aa) in the subparagraph
 heading, by striking “NURSE
 AIDE”; and
 (bb) in clause (i), in the
 matter preceding subclause (I),
 by striking “a nurse aide” and
 inserting “an individual”; and
 (cc) in clause (i)(I), by striking
 “nurse aide” and inserting
 “individual”.

(d) REIMBURSEMENT OF COSTS FOR BACKGROUND CHECKS.—The Secretary of Health and Human Services shall reimburse nursing facilities, skilled nursing facilities, and other entities for costs incurred by the facilities and entities in order to comply with the requirements imposed under sections 1819(b)(8) and 1919(b)(8) of such Act (42 U.S.C. 1395i-3(b)(8), 1396r(b)(8)), as added by this section.

(e) INCLUSION OF ABUSIVE ACTS WITHIN A LONG-TERM CARE FACILITY OR PROVIDER IN THE NATIONAL HEALTH CARE FRAUD AND ABUSE DATA COLLECTION PROGRAM.—

(1) IN GENERAL.—Section 1128E(g)(1)(A) (42 U.S.C. 1320a-7e(g)(1)(A)) is amended—

(A) by redesignating clause (v) as clause (vi); and

(B) by inserting after clause (iv), the following:

“(v) A finding of abuse or neglect of a patient or a resident of a long-term care facility, or misappropriation of such a patient’s or resident’s property.”.

(2) COVERAGE OF LONG-TERM CARE FACILITY OR PROVIDER EMPLOYEES.—Section 1128E(g)(2) (42 U.S.C. 1320a-7e(g)(2)) is amended by inserting

1 “, and includes any individual of a long-term care
 2 facility or provider (other than any volunteer) that
 3 has access to a patient or resident of such a facility
 4 under an employment or other contract, or both,
 5 with the facility or provider (including individuals
 6 who are licensed or certified by the State to provide
 7 services at the facility or through the provider, and
 8 nonlicensed individuals, as defined by the Secretary,
 9 providing services at the facility or through the pro-
 10 vider, including nurse assistants, nurse aides, home
 11 health aides, individuals who provide home care, and
 12 personal care workers and attendants)” before the
 13 period.

14 (3) REPORTING BY LONG-TERM CARE FACILI-
 15 TIES OR PROVIDERS.—

16 (A) IN GENERAL.—Section 1128E(b)(1)
 17 (42 U.S.C. 1320a-7e(b)(1)) is amended by
 18 striking “and health plan” and inserting “,
 19 health plan, and long-term care facility or pro-
 20 vider”.

21 (B) CORRECTION OF INFORMATION.—Sec-
 22 tion 1128E(c)(2) (42 U.S.C. 1320a-7e(c)(2)) is
 23 amended by striking “and health plan” and in-
 24 serting “, health plan, and long-term care facil-
 25 ity or provider”.

1 (4) ACCESS TO REPORTED INFORMATION.—Sec-
 2 tion 1128E(d)(1) (42 U.S.C. 1320a-7e(d)(1)) is
 3 amended by striking “and health plans” and insert-
 4 ing “, health plans, and long-term care facilities or
 5 providers”.

6 (5) MANDATORY CHECK OF DATABASE BY
 7 LONG-TERM CARE FACILITIES OR PROVIDERS.—Sec-
 8 tion 1128E(d) (42 U.S.C. 1320a-7e(d)) is amended
 9 by adding at the end the following:

10 “(3) MANDATORY CHECK OF DATABASE BY
 11 LONG-TERM CARE FACILITIES OR PROVIDERS.—A
 12 long-term care facility or provider shall check the
 13 database maintained under this section prior to hir-
 14 ing under an employment or other contract, or both,
 15 (other than in a provisional status) any individual as
 16 an employee of such a facility or provider who will
 17 have access to a patient or resident of the facility or
 18 provider (including individuals who are licensed or
 19 certified by the State to provide services at the facil-
 20 ity or through the provider, and nonlicensed individ-
 21 uals, as defined by the Secretary, that will provide
 22 services at the facility or through the provider, in-
 23 cluding nurse assistants, nurse aides, home health
 24 aides, individuals who provide home care, and per-
 25 sonal care workers and attendants).”.

(6) DEFINITION OF LONG-TERM CARE FACILITY OR PROVIDER.—Section 1128E(g) (42 U.S.C. 1320a-7e(g)) is amended by adding at the end the following:

“(6) LONG-TERM CARE FACILITY OR PROVIDER.—The term ‘long-term care facility or provider’ means a skilled nursing facility (as defined in section 1819(a)), a nursing facility (as defined in section 1919(a)), a home health agency, a provider of hospice care (as defined in section 1861(dd)(1)), a long-term care hospital (as described in section 1886(d)(1)(B)(iv)), an intermediate care facility for the mentally retarded (as defined in section 1905(d)), or any other facility or entity that provides, or is a provider of, long-term care services, home health services, or hospice care (including routine home care and other services included in hospice care under title XVIII), and receives payment for such services under the medicare program under title XVIII or the medicaid program under title XIX.”.

(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out the amendments made by this subsection, \$10,200,000 for fiscal year 2004.

1 (f) PREVENTION AND TRAINING DEMONSTRATION
2 PROJECT.—

3 (1) ESTABLISHMENT.—The Secretary of Health
4 and Human Services shall establish a demonstration
5 program to provide grants to develop information on
6 best practices in patient abuse prevention training
7 (including behavior training and interventions) for
8 managers and staff of hospital and health care fa-
9 cilities.

10 (2) ELIGIBILITY.—To be eligible to receive a
11 grant under paragraph (1), an entity shall be a pub-
12 lic or private nonprofit entity and prepare and sub-
13 mit to the Secretary of Health and Human Services
14 an application at such time, in such manner, and
15 containing such information as the Secretary may
16 require.

17 (3) USE OF FUNDS.—Amounts received under a
18 grant under this subsection shall be used to—

19 (A) examine ways to improve collaboration
20 between State health care survey and provider
21 certification agencies, long-term care ombuds-
22 man programs, the long-term care industry,
23 and local community members;

24 (B) examine patient care issues relating to
25 regulatory oversight, community involvement,

and facility staffing and management with a focus on staff training, staff stress management, and staff supervision; ~~and~~

(C) examine the use of patient abuse prevention training programs by long-term care entities, including the training program developed by the National Association of Attorneys General, and the extent to which such programs are used; and ~~the extent to which such programs are used; and~~

(D) identify and disseminate best practices for preventing and reducing patient abuse.

(4) AUTHORIZATION OF APPROPRIATIONS.—

There is authorized to be appropriated such sums as may be necessary to carry out this subsection. ~~and~~

(g) EFFECTIVE DATE.— ~~As amended~~

(1) IN GENERAL.—With respect to a skilled nursing facility (as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395i-3(a)) or a nursing facility (as defined in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a))), this section and the amendments made by this section shall take effect on the date that is the earlier of—

(A) 6 months after the effective date of final regulations promulgated to carry out this section and such amendments; or ~~and~~ ~~and~~

(B) January 1, 2006.

(2) LONG-TERM CARE FACILITIES AND PROVIDERS.—With respect to a long-term care facility or provider (as defined in section 1128E(g)(6) of the Social Security Act (42 U.S.C. 1320a-7e(g)(6)) (as added by subsection (e)), this section and the amendments made by this section shall take effect on the date that is the earlier of—

(A) 18 months after the effective date of final regulations promulgated to carry out this section and such amendments; or

(B) January 1, 2007.

SEC. 637. OFFICE OF RURAL HEALTH POLICY IMPROVEMENTS.

Section 711(b) (42 U.S.C. 912(b)) is amended—

(1) in paragraph (3), by striking “and” after the comma at the end;

(2) in paragraph (4), by inserting “and” after the comma at the end; and

(3) by inserting after paragraph (4) the following new paragraph:

“(5) administer grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas.”.

1 **TITLE VII—ACCESS TO AFFORD-** 2 **ABLE PHARMACEUTICALS**

3 **SEC. 701. SHORT TITLE.**

4 This title may be cited as the “Greater Access to Af-
5 fordable Pharmaceuticals Act”.

6 **SEC. 702. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.**

7 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
8 tion 505(j) of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 355(j)) is amended—

10 (1) in paragraph (2), by striking subparagraph
11 (B) and inserting the following:

12 “(B) NOTICE OF OPINION THAT PATENT IS INVALID
13 OR WILL NOT BE INFRINGED.—

14 “(i) AGREEMENT TO GIVE NOTICE.—An appli-
15 cant that makes a certification described in subpara-
16 graph (A)(vii)(IV) shall include in the application a
17 statement that the applicant will give notice as re-
18 quired by this subparagraph.

19 “(ii) TIMING OF NOTICE.—An applicant that
20 makes a certification described in subparagraph
21 (A)(vii)(IV) shall give notice as required under this
22 subparagraph—

23 “(I) if the certification is in the applica-
24 tion, not later than 20 days after the date of
25 the postmark on the notice with which the Sec-

1 retary informs the applicant that the applica-
2 tion has been filed; or

3 “(II) if the certification is in an amend-
4 ment or supplement to the application, at the
5 time at which the applicant submits the amend-
6 ment or supplement, regardless of whether the
7 applicant has already given notice with respect
8 to another such certification contained in the
9 application or in an amendment or supplement
10 to the application.

11 “(iii) RECIPIENTS OF NOTICE.—An applicant
12 required under this subparagraph to give notice shall
13 give notice to—

14 “(I) each owner of the patent that is the
15 subject of the certification (or a representative
16 of the owner designated to receive such a no-
17 tice); and

18 “(II) the holder of the approved applica-
19 tion under subsection (b) for the drug that is
20 claimed by the patent or a use of which is
21 claimed by the patent (or a representative of
22 the holder designated to receive such a notice).

23 “(iv) CONTENTS OF NOTICE.—A notice required
24 under this subparagraph shall—

“(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

“(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.”; and

(2) in paragraph (5)—

(A) in subparagraph (B)—

(i) by striking “under the following” and inserting “by applying the following to each certification made under paragraph (2)(A)(vii)”; and

(ii) in clause (iii)—

(I) in the first sentence, by striking “unless” and all that follows and inserting “unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is

1 brought for infringement of the patent
 2 that is the subject of the certification
 3 and for which information was sub-
 4 mitted to the Secretary under sub-
 5 section (b)(1) or (c)(2) before the date
 6 on which the application (excluding an
 7 amendment or supplement to the ap-
 8 plication), which the Secretary later
 9 determines to be substantially com-
 10 plete, was submitted.”; and

11 (II) in the second sentence—

12 (aa) by striking subclause
 13 (I) and inserting the following:

14 “(I) if before the expiration of such period
 15 the district court decides that the patent is in-
 16 valid or not infringed (including any substantive
 17 determination that there is no cause of action
 18 for patent infringement or invalidity), the ap-
 19 proval shall be made effective on—

20 “(aa) the date on which the court en-
 21 ters judgment reflecting the decision; or

22 “(bb) the date of a settlement order
 23 or consent decree signed and entered by
 24 the court stating that the patent that is

the subject of the certification is invalid or
not infringed;”;

and (bb) by striking subclause

(II) and inserting the following:

“(II) if before the expiration of such period
the district court decides that the patent has
been infringed—

“(aa) if the judgment of the district
court is appealed, the approval shall be
not made effective on—

“(AA) the date on which the
court of appeals decides that the pat-
ent is invalid or not infringed (includ-
ing any substantive determination
that there is no cause of action for
patent infringement or invalidity); or

“(BB) the date of a settlement
order or consent decree signed and
entered by the court of appeals stat-
ing that the patent that is the subject
of the certification is invalid or not in-
fringed; or

“(bb) if the judgment of the district
court is not appealed or is affirmed, the
approval shall be made effective on the

1 date specified by the district court in a
2 court order under section 271(e)(4)(A) of
3 title 35, United States Code;”;

4 (cc) in subclause (III), by
5 striking “on the date of such
6 court decision.” and inserting “as
7 provided in subclause (I); or”;
8 and

9 (dd) by inserting after sub-
10 clause (III) the following:

11 “(IV) if before the expiration of such pe-
12 riod the court grants a preliminary injunction
13 prohibiting the applicant from engaging in the
14 commercial manufacture or sale of the drug
15 until the court decides the issues of patent va-
16 lidity and infringement and if the court decides
17 that such patent has been infringed, the ap-
18 proval shall be made effective as provided in
19 subclause (II).”;

20 (B) by redesignating subparagraphs (C)
21 and (D) as subparagraphs (E) and (F), respec-
22 tively; and

23 (C) by inserting after subparagraph (B)
24 the following:

“(C) CIVIL ACTION TO OBTAIN PATENT
CERTAINTY.—

“(i) DECLARATORY JUDGMENT AB-
SENT INFRINGEMENT ACTION.—If an
owner of the patent or the holder of the
approved application under subsection (b)
for the drug that is claimed by the patent
or a use of which is claimed by the patent
does not bring a civil action against the
applicant for infringement of the patent on
or before the date that is 45 days after the
date on which the notice given under para-
graph (2)(B) was received, the applicant
may bring a civil action against the owner
or holder (but not against any owner or
holder that has brought such a civil action
against that applicant, unless that civil ac-
tion was dismissed without prejudice) for a
declaratory judgment under section 2201
of title 28, United States Code, that the
patent is invalid or will not be infringed by
the drug for which the applicant seeks ap-
proval.

“(ii) COUNTERCLAIM TO INFRINGE-
MENT ACTION.—

1 “(I) IN GENERAL.—If an owner
2 of the patent or the holder of the ap-
3 proved application under subsection
4 (b) for the drug that is claimed by the
5 patent or a use of which is claimed by
6 the patent brings a patent infringe-
7 ment action against the applicant, the
8 applicant may assert a counterclaim
9 seeking an order requiring the holder
10 to correct or delete the patent infor-
11 mation submitted by the holder under
12 subsection (b) or (c) on the ground
13 that the patent does not claim ei-
14 ther—

15 “(aa) the drug for which the
16 application was approved; or

17 “(bb) an approved method
18 of using the drug.

19 “(II) NO INDEPENDENT CAUSE
20 OF ACTION.—Subclause (I) does not
21 authorize the assertion of a claim de-
22 scribed in subclause (I) in any civil
23 action or proceeding other than a
24 counterclaim described in subclause
25 (I).

“(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under subparagraph (i) or a counterclaim under subparagraph (ii).”.

(b) APPLICATIONS GENERALLY.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b), by striking paragraph (3) and inserting the following:

“(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

“(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

“(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

“(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

1 “(ii) if the certification is in an amend-
 2 ment or supplement to the application, at the
 3 time at which the applicant submits the amend-
 4 ment or supplement, regardless of whether the
 5 applicant has already given notice with respect
 6 to another such certification contained in the
 7 application or in an amendment or supplement
 8 to the application. (11)

9 “(C) RECIPIENTS OF NOTICE.—An applicant
 10 required under this paragraph to give notice shall
 11 give notice to— (12) (13) (14) (15) (16) (17) (18) (19) (20) (21) (22) (23) (24) (25)

12 “(i) each owner of the patent that is the
 13 subject of the certification (or a representative
 14 of the owner designated to receive such a no-
 15 tice); and (16) (17) (18) (19) (20) (21) (22) (23) (24) (25)

16 “(ii) the holder of the approved application
 17 under this subsection for the drug that is
 18 claimed by the patent or a use of which is
 19 claimed by the patent (or a representative of
 20 the holder designated to receive such a notice).

21 “(D) CONTENTS OF NOTICE.—A notice re-
 22 quired under this paragraph shall—

23 “(i) state that an application that contains
 24 data from bioavailability or bioequivalence stud-
 25 ies has been submitted under this subsection for

the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.”; and

(2) in subsection (c)(3)—

(A) in the first sentence, by striking “under the following” and inserting “by applying the following to each certification made under subsection (b)(2)(A)(iv)”;

(B) in subparagraph (C)—

(i) in the first sentence, by striking “unless” and all that follows and inserting “unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on

1 which the application (excluding an amend-
 2 ment or supplement to the application) was
 3 submitted.”;

4 (ii) in the second sentence—

5 (I) by striking “paragraph
 6 (3)(B)” and inserting “subsection
 7 (b)(3)”;

8 (II) by striking clause (i) and in-
 9 serting the following:

10 “(i) if before the expiration of such period
 11 the district court decides that the patent is in-
 12 valid or not infringed (including any substantive
 13 determination that there is no cause of action
 14 for patent infringement or invalidity), the ap-
 15 proval shall be made effective on—

16 “(I) the date on which the court en-
 17 ters judgment reflecting the decision; or

18 “(II) the date of a settlement order or
 19 consent decree signed and entered by the
 20 court stating that the patent that is the
 21 subject of the certification is invalid or not
 22 infringed.”;

23 (III) by striking clause (ii) and
 24 inserting the following:

1 (iii) “(ii) if before the expiration of such period
2 the district court decides that the patent has
3 been infringed—

4 “(I) if the judgment of the district
5 court is appealed, the approval shall be
6 made effective on—

7 ~~reference to~~ “(aa) the date on which the court
8 of appeals decides that the patent is
9 invalid or not infringed (including any
10 substantive determination that there
11 ~~is no cause of action for patent in-~~
12 ~~fringement or invalidity); or~~

13 ~~reference to~~ “(bb) the date of a settlement
14 order or consent decree signed and
15 entered by the court of appeals stat-
16 ~~ing that the patent that is the subject~~
17 of the certification is invalid or not in-
18 fringed; or

19 “(II) if the judgment of the district
20 court is not appealed or is affirmed, the
21 ~~approval~~ approval shall be made effective on the
22 date specified by the district court in a
23 court order under section 271(e)(4)(A) of
24 title 35, United States Code;”;

1 (IV) in clause (iii), by striking

2 ~~the words "on the date of such court decision."~~

3 and inserting "as provided in clause

4 ~~of the Act~~ (i); or"; and

5 ~~in clause (V)~~ (V) by inserting after clause (iii),

6 the following:

7 "(iv) if before the expiration of such period

8 the court grants a preliminary injunction pro-

9 ~~hibiting~~hibiting the applicant from engaging in the

10 ~~in~~ commercial manufacture or sale of the drug

11 until the court decides the issues of patent va-

12 lidity and infringement and if the court decides

13 that such patent has been infringed, the ap-

14 proval shall be made effective as provided in

15 clause (ii)."; and

16 (iii) in the third sentence, by striking

17 ~~the words "paragraph (3)(B)"~~ "paragraph (3)(B)" and inserting "sub-

18 section (b)(3)";

19 (C) by redesignating subparagraph (D) as

20 subparagraph (E); and

21 (D) by inserting after subparagraph (C)

22 the following:

23 "(D) CIVIL ACTION TO OBTAIN PATENT

24 CERTAINTY.—

“(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent does not bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice given under subsection (b)(3) was received, the applicant may bring a civil action against the owner or holder (but not against any owner or holder that has brought such a civil action against that applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment under section 2201 of title 28, United States Code, that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

“(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

“(I) IN GENERAL.—If an owner of the patent or the holder of the ap-

1 proved application under subsection
 2 (b) for the drug that is claimed by the
 3 patent or a use of which is claimed by
 4 the patent brings a patent infringe-
 5 ment action against the applicant, the
 6 applicant may assert a counterclaim
 7 seeking an order requiring the holder
 8 to correct or delete the patent infor-
 9 mation submitted by the holder under
 10 subsection (b) or this subsection on
 11 the ground that the patent does not
 12 claim either—

13 “(aa) the drug for which the
 14 application was approved; or

15 “(bb) an approved method
 16 of using the drug.

17 “(II) NO INDEPENDENT CAUSE
 18 OF ACTION.—Subclause (I) does not
 19 authorize the assertion of a claim de-
 20 scribed in subclause (I) in any civil
 21 action or proceeding other than a
 22 counterclaim described in subclause
 23 (I).

24 “(iii) NO DAMAGES.—An applicant
 25 shall not be entitled to damages in a civil

action under clause (i) or a counterclaim
under clause (ii).”.

(c) INFRINGEMENT ACTIONS.—Section 271(e) of title
35, United States Code, is amended by adding at the end
the following:

“(5) The filing of an application described in
paragraph (2) that includes a certification under
subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of sec-
tion 505 of the Federal Food, Drug, and Cosmetic
Act (21 U.S.C. 355), and the failure of the owner
of the patent to bring an action for infringement of
a patent that is the subject of the certification be-
fore the expiration of 45 days after the date on
which the notice given under subsection (b)(3) or
(j)(2)(B) of that section is received, shall establish
an actual controversy between the applicant and the
patent owner sufficient to confer subject matter ju-
risdiction in the courts of the United States in any
action brought by the applicant under section 2201
of title 28 for a declaratory judgment that any pat-
ent that is the subject of the certification is invalid
or not infringed.”.

(d) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in para-
graphs (2) and (3), the amendments made by sub-

1 sections (a), (b), and (c) apply to any proceeding
2 under section 505 of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355) that is pending on or
4 after the date of enactment of this Act regardless of
5 the date on which the proceeding was commenced or
6 is commenced.

7 (2) NOTICE OF OPINION THAT PATENT IS IN-
8 VALID OR WILL NOT BE INFRINGED.—The amend-
9 ments made by subsections (a)(1) and (b)(1) apply
10 with respect to any certification under subsection
11 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of
12 the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 355) after the date of enactment of this Act
14 in an application filed under subsection (b)(2) or (j)
15 of that section or in an amendment or supplement
16 to an application filed under subsection (b)(2) or (j)
17 of that section.

18 (3) EFFECTIVE DATE OF APPROVAL.—The
19 amendments made by subsections (a)(2)(A)(ii)(I)
20 and (b)(2)(B)(i) apply with respect to any patent in-
21 formation submitted under subsection (b)(1) or
22 (c)(2) of section 505 of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355) made after the date
24 of enactment of this Act.

1 **SEC. 703. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

2 (a) IN GENERAL.—Section 505(j)(5) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as
4 amended by section 702) is amended—

5 (1) in subparagraph (B), by striking clause (iv)
6 and inserting the following:

7 “(iv) 180-DAY EXCLUSIVITY PERIOD.—

8 “(I) DEFINITIONS.—In this paragraph:

9 “(aa) 180-DAY EXCLUSIVITY PE-
10 RIOD.—The term ‘180-day exclusivity pe-
11 riod’ means the 180-day period ending on
12 the day before the date on which an appli-
13 cation submitted by an applicant other
14 than a first applicant could become effec-
15 tive under this clause.

16 “(bb) FIRST APPLICANT.—The term
17 ‘first applicant’ means an applicant that,
18 on the first day on which a substantially
19 complete application containing a certifi-
20 cation described in paragraph
21 (2)(A)(vii)(IV) is submitted for approval of
22 a drug, submits a substantially complete
23 application containing a certification de-
24 scribed in paragraph (2)(A)(vii)(IV) for
25 the drug.

1 ~~“(cc) TENTATIVE APPROVAL.”~~“(cc) SUBSTANTIALLY COMPLETE AP-
 2 ~~PROVAL.”~~PLICATION.—As used in this subsection,
 3 the term ‘substantially complete applica-
 4 tion’ means an application under this sub-
 5 section that on its face is sufficiently com-
 6 plete to permit a substantive review and
 7 ~~approval~~ contains all the information required by
 8 ~~section 505(b)(1)(A)~~ paragraph (2)(A).

9 “(dd) TENTATIVE APPROVAL.—

10 ~~“(dd) TENTATIVE APPROVAL.”~~“(AA) IN GENERAL.—The term
 11 ~~“(dd) TENTATIVE APPROVAL.”~~‘tentative approval’ means notification
 12 ~~“(dd) TENTATIVE APPROVAL.”~~to an applicant by the Secretary that
 13 an application under this subsection
 14 meets the requirements of paragraph
 15 (2)(A), but cannot receive effective
 16 approval because the application does
 17 not meet the requirements of this sub-
 18 ~~“(dd) TENTATIVE APPROVAL.”~~paragraph, there is a period of exclu-
 19 ~~“(dd) TENTATIVE APPROVAL.”~~sivity for the listed drug under sub-
 20 paragraph (E) or section 505A, or
 21 ~~“(dd) TENTATIVE APPROVAL.”~~there is a 7-year period of exclusivity
 22 ~~“(dd) TENTATIVE APPROVAL.”~~for the listed drug under section 527.

23 ~~“(dd) TENTATIVE APPROVAL.”~~“(BB) LIMITATION.—A drug
 24 ~~“(dd) TENTATIVE APPROVAL.”~~that is granted tentative approval by
 25 the Secretary is not an approved drug

and shall not have an effective application until the Secretary issues an approval after any necessary additional review of the application.

“(II) EFFECTIVENESS OF APPLICATION.—

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.”; and

(2) by inserting after subparagraph (C) the following:

“(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

“(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term ‘forfeiture event’, with respect to an application under this subsection, means the occurrence of any of the following:

1 “(I) FAILURE TO MARKET.—The
2 first applicant fails to market the
3 drug by the later of—

4 “(aa) the earlier of the date
5 that is—

6 “(AA) 75 days after the
7 date on which the approval
8 of the application of the first
9 applicant is made effective
10 under subparagraph (B)(iii);
11 or

12 “(BB) 30 months after
13 the date of submission of
14 the application of the first
15 applicant; or

16 “(bb) with respect to the
17 first applicant or any other appli-
18 cant (which other applicant has
19 received tentative approval), the
20 date that is 75 days after the
21 date as of which, as to each of
22 the patents with respect to which
23 the first applicant submitted a
24 certification qualifying the first
25 applicant for the 180-day exclu-

hesitivity period under subparagraph
(B)(iv), at least 1 of the fol-
lowing has occurred:

“(AA) In an infringe-
ment action brought against
that applicant with respect
to the patent or in a declar-
atory judgment action
brought by that applicant

with respect to the patent, a
court enters a final decision
from which no appeal (other
than a petition to the Su-
preme Court for a writ of
certiorari) has been or can
be taken that the patent is
invalid or not infringed.

“(BB) In an infringe-
ment action or a declaratory
judgment action described in
subitem (AA), a court signs
a settlement order or con-
sent decree that enters a
final judgment that includes

1 a finding that the patent is
2 invalid or not infringed.

3 “(CC) The patent ex-
4 pires.

5 “(DD) The patent is
6 withdrawn by the holder of
7 the application approved
8 under subsection (b).

9 “(II) WITHDRAWAL OF APPLICA-
10 TION.—The first applicant withdraws
11 the application or the Secretary con-
12 siders the application to have been
13 withdrawn as a result of a determina-
14 tion by the Secretary that the applica-
15 tion does not meet the requirements
16 for approval under paragraph (4).

17 “(III) AMENDMENT OF CERTIFI-
18 CATION.—The first applicant amends
19 or withdraws the certification for all
20 of the patents with respect to which
21 that applicant submitted a certifi-
22 cation qualifying the applicant for the
23 180-day exclusivity period.

24 “(IV) FAILURE TO OBTAIN TEN-
25 TATIVE APPROVAL.—The first appli-

1 to applicant fails to obtain tentative approval
 2 of the application within 30 months
 3 after the date on which the applica-
 4 tion is filed, unless the failure is
 5 caused by a change in or a review of
 6 the requirements for approval of the
 7 application imposed after the date on
 8 which the application is filed.

9 “(V) AGREEMENT WITH AN-
 10 OTHER APPLICANT, THE LISTED DRUG
 11 APPLICATION HOLDER, OR A PATENT
 12 OWNER.—The first applicant enters
 13 into an agreement with another appli-
 14 cant under this subsection for the
 15 drug, the holder of the application for
 16 the listed drug, or an owner of the
 17 patent that is the subject of the cer-
 18 tification under paragraph
 19 (2)(A)(vii)(IV), the Federal Trade
 20 Commission or the Attorney General
 21 files a complaint, and there is a final
 22 decision of the Federal Trade Com-
 23 mission or the court with regard to
 24 the complaint from which no appeal
 25 (other than a petition to the Supreme

1 Court for a writ of certiorari) has
2 been or can be taken that the agree-
3 ment has violated the antitrust laws
4 (as defined in section 1 of the Clayton
5 Act (15 U.S.C. 12), except that the
6 term includes section 5 of the Federal
7 Trade Commission Act (15 U.S.C. 45)
8 to the extent that that section applies
9 to unfair methods of competition).

10 “(VI) EXPIRATION OF ALL PAT-
11 ENTS.—All of the patents as to which
12 the applicant submitted a certification
13 qualifying it for the 180-day exclu-
14 sivity period have expired.

15 “(ii) FORFEITURE.—The 180-day ex-
16 clusivity period described in subparagraph
17 (B)(iv) shall be forfeited by a first appli-
18 cant if a forfeiture event occurs with re-
19 spect to that first applicant.

20 “(iii) SUBSEQUENT APPLICANT.—If
21 all first applicants forfeit the 180-day ex-
22 clusivity period under clause (ii)—

23 “(I) approval of any application
24 containing a certification described in
25 paragraph (2)(A)(vii)(IV) shall be

1 196, and 197 made effective in accordance with sub-
 2 196, 197, and 198 paragraph (B)(iii); and 199

3 200, 201, and 202 “(II) no applicant shall be eligi-
 4 203 ble for a 180-day exclusivity period.”.

5 (b) EFFECTIVE DATE.— 204, 205, 206, 207, 208, 209

6 (1) IN GENERAL.—Except as provided in para-
 7 graph (2), the amendment made by subsection (a)
 8 shall be effective only with respect to an application
 9 filed under section 505(j) of the Federal Food,
 10 Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the
 11 date of enactment of this Act for a listed drug for
 12 which no certification under section
 13 505(j)(2)(A)(vii)(IV) of that Act was made before
 14 the date of enactment of this Act. 210, 211, 212, 213, 214

15 (2) COLLUSIVE AGREEMENTS.—If a forfeiture
 16 event described in section 505(j)(5)(D)(i)(V) of that
 17 Act occurs in the case of an applicant, the applicant
 18 shall forfeit the 180-day period under section
 19 505(j)(5)(B)(iv) of that Act without regard to when
 20 the first certification under section
 21 505(j)(2)(A)(vii)(IV) of that Act for the listed drug
 22 was made. 215, 216, 217, 218, 219

23 (3) DECISION OF A COURT WHEN THE 180-DAY
 24 EXCLUSIVITY PERIOD HAS NOT BEEN TRIGGERED.—
 25 With respect to an application filed before, on, or

1 after the date of enactment of this Act for a listed
2 drug for which a certification under section
3 505(j)(2)(A)(vii)(IV) of that Act was made before
4 the date of enactment of this Act and for which nei-
5 ther of the events described in subclause (I) or (II)
6 of section 505(j)(5)(B)(iv) of that Act (as in effect
7 on the day before the date of enactment of this Act)
8 has occurred on or before the date of enactment of
9 this Act, the term “decision of a court” as used in
10 clause (iv) of section 505(j)(5)(B) of that Act means
11 a final decision of a court from which no appeal
12 (other than a petition to the Supreme Court for a
13 writ of certiorari) has been or can be taken.

14 **SEC. 704. BIOAVAILABILITY AND BIOEQUIVALENCE.**

15 (a) IN GENERAL.—Section 505(j)(8) of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is
17 amended—

18 (1) by striking subparagraph (A) and inserting
19 the following:

20 “(A)(i) The term ‘bioavailability’ means the
21 rate and extent to which the active ingredient or
22 therapeutic ingredient is absorbed from a drug and
23 becomes available at the site of drug action.

24 “(ii) For a drug that is not intended to be ab-
25 sorbed into the bloodstream, the Secretary may as-

1 sess bioavailability by scientifically valid measure-
2 ments intended to reflect the rate and extent to
3 which the active ingredient or therapeutic ingredient
4 becomes available at the site of drug action.”; and

5 (2) by adding at the end the following:

6 “(C) For a drug that is not intended to be ab-
7 sorbed into the bloodstream, the Secretary may es-
8 tablish alternative, scientifically valid methods to
9 show bioequivalence if the alternative methods are
10 expected to detect a significant difference between
11 the drug and the listed drug in safety and thera-
12 peutic effect.”.

13 (b) EFFECT OF AMENDMENT.—The amendment
14 made by subsection (a) does not alter the standards for
15 approval of drugs under section 505(j) of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

17 **SEC. 705. REMEDIES FOR INFRINGEMENT.**

18 Section 287 of title 35, United States Code, is
19 amended by adding at the end the following:

20 “(d) CONSIDERATION.—In making a determination
21 with respect to remedy brought for infringement of a pat-
22 ent that claims a drug or a method or using a drug, the
23 court shall consider whether information on the patent
24 was filed as required under 21 U.S.C. 355 (b) or (c), and,
25 if such information was required to be filed but was not,

1 the court may refuse to award treble damages under sec-
2 tion 284.”.

3 **SEC. 706. CONFORMING AMENDMENTS.**

4 Section 505A of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355a) is amended—

6 (1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i),
7 by striking “(j)(5)(D)(ii)” each place it appears and
8 inserting “(j)(5)(F)(ii)”;

9 (2) in subsections (b)(1)(A)(ii) and
10 (c)(1)(A)(ii), by striking “(j)(5)(D)” each place it
11 appears and inserting “(j)(5)(F)”;

12 (3) in subsections (e) and (l), by striking
13 “505(j)(5)(D)” each place it appears and inserting
14 “505(j)(5)(F)”.

15 **TITLE VIII—IMPORTATION OF** 16 **PRESCRIPTION DRUGS**

17 **SEC. 801. IMPORTATION OF PRESCRIPTION DRUGS.**

18 (a) IN GENERAL.—Chapter VIII of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
20 is amended by striking section 804 and inserting the fol-
21 lowing:

22 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

23 “(a) DEFINITIONS.—In this section:

24 “(1) IMPORTER.—The term ‘importer’ means a
25 pharmacist or wholesaler.

1 “(2) PHARMACIST.—The term ‘pharmacist’
 2 means a person licensed by a State to practice phar-
 3 macy, including the dispensing and selling of pre-
 4 scription drugs.

5 “(3) PRESCRIPTION DRUG.—The term ‘pre-
 6 scription drug’ means a drug subject to section
 7 503(b), other than—

8 “(A) a controlled substance (as defined in
 9 section 102 of the Controlled Substances Act
 10 (21 U.S.C. 802));

11 “(B) a biological product (as defined in
 12 section 351 of the Public Health Service Act
 13 (42 U.S.C. 262));

14 “(C) an infused drug (including a peri-
 15 toneal dialysis solution);

16 “(D) an intravenously injected drug; or

17 “(E) a drug that is inhaled during surgery.

18 “(4) QUALIFYING LABORATORY.—The term
 19 ‘qualifying laboratory’ means a laboratory in the
 20 United States that has been approved by the Sec-
 21 retary for the purposes of this section.

22 “(5) WHOLESALER.—

23 “(A) IN GENERAL.—The term ‘wholesaler’
 24 means a person licensed as a wholesaler or dis-

1 tributor of prescription drugs in the United
2 States under section 503(e)(2)(A).

3 “(B) EXCLUSION.—The term ‘wholesaler’
4 does not include a person authorized to import
5 drugs under section 801(d)(1).

6 “(b) REGULATIONS.—The Secretary, after consulta-
7 tion with the United States Trade Representative and the
8 Commissioner of Customs, shall promulgate regulations
9 permitting pharmacists and wholesalers to import pre-
10 scription drugs from Canada into the United States.

11 “(c) LIMITATION.—The regulations under subsection
12 (b) shall—

13 “(1) require that safeguards be in place to en-
14 sure that each prescription drug imported under the
15 regulations complies with section 505 (including
16 with respect to being safe and effective for the in-
17 tended use of the prescription drug), with sections
18 501 and 502, and with other applicable require-
19 ments of this Act;

20 “(2) require that an importer of a prescription
21 drug under the regulations comply with subsections
22 (d)(1) and (e); and

23 “(3) contain any additional provisions deter-
24 mined by the Secretary to be appropriate as a safe-

guard to protect the public health or as a means to facilitate the importation of prescription drugs.

“(d) INFORMATION AND RECORDS.—

“(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

“(A) The name and quantity of the active ingredient of the prescription drug.

“(B) A description of the dosage form of the prescription drug.

“(C) The date on which the prescription drug is shipped.

“(D) The quantity of the prescription drug that is shipped.

“(E) The point of origin and destination of the prescription drug.

“(F) The price paid by the importer for the prescription drug.

“(G) Documentation from the foreign seller specifying—

“(i) the original source of the prescription drug; and

1 “(ii) the quantity of each lot of the
2 prescription drug originally received by the
3 seller from that source.

4 “(H) The lot or control number assigned
5 to the prescription drug by the manufacturer of
6 the prescription drug.

7 “(I) The name, address, telephone number,
8 and professional license number (if any) of the
9 importer.

10 “(J)(i) In the case of a prescription drug
11 that is shipped directly from the first foreign
12 recipient of the prescription drug from the
13 manufacturer:

14 “(I) Documentation demonstrating
15 that the prescription drug was received by
16 the recipient from the manufacturer and
17 subsequently shipped by the first foreign
18 recipient to the importer.

19 “(II) Documentation of the quantity
20 of each lot of the prescription drug re-
21 ceived by the first foreign recipient dem-
22 onstrating that the quantity being im-
23 ported into the United States is not more
24 than the quantity that was received by the
25 first foreign recipient.

“(III)(aa) In the case of an initial im-
ported shipment, documentation dem-
onstrating that each batch of the prescrip-
tion drug in the shipment was statistically
sampled and tested for authenticity and
degradation.

“(bb) In the case of any subsequent
shipment, documentation demonstrating
that a statistically valid sample of the ship-
ment was tested for authenticity and deg-
radation.

“(ii) In the case of a prescription drug
that is not shipped directly from the first for-
eign recipient of the prescription drug from the
manufacturer, documentation demonstrating
that each batch in each shipment offered for
importation into the United States was statis-
tically sampled and tested for authenticity and
degradation.

“(K) Certification from the importer or
manufacturer of the prescription drug that the
prescription drug—

“(i) is approved for marketing in the
United States; and

1 “(ii) meets all labeling requirements
2 under this Act.

3 “(L) Laboratory records, including com-
4 plete data derived from all tests necessary to
5 ensure that the prescription drug is in compli-
6 ance with established specifications and stand-
7 ards.

8 “(M) Documentation demonstrating that
9 the testing required by subparagraphs (J) and
10 (L) was conducted at a qualifying laboratory.

11 “(N) Any other information that the Sec-
12 retary determines is necessary to ensure the
13 protection of the public health.

14 “(2) MAINTENANCE BY THE SECRETARY.—The
15 Secretary shall maintain information and docu-
16 mentation submitted under paragraph (1) for such
17 period of time as the Secretary determines to be nec-
18 essary.

19 “(e) TESTING.—The regulations under subsection (b)
20 shall require—

21 “(1) that testing described in subparagraphs
22 (J) and (L) of subsection (d)(1) be conducted by the
23 importer or by the manufacturer of the prescription
24 drug at a qualified laboratory;

“(2) if the tests are conducted by the importer—

“(A) that information needed to—

“(i) authenticate the prescription drug being tested; and

“(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

“(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

“(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

“(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Sec-

1 retary the name and place of business of the establish-
2 ment.

3 “(g) SUSPENSION OF IMPORTATION.—The Secretary
4 shall require that importations of a specific prescription
5 drug or importations by a specific importer under sub-
6 section (b) be immediately suspended on discovery of a
7 pattern of importation of that specific prescription drug
8 or by that specific importer of drugs that are counterfeit
9 or in violation of any requirement under this section, until
10 an investigation is completed and the Secretary deter-
11 mines that the public is adequately protected from coun-
12 terfeit and violative prescription drugs being imported
13 under subsection (b).

14 “(h) APPROVED LABELING.—The manufacturer of a
15 prescription drug shall provide an importer written au-
16 thorization for the importer to use, at no cost, the ap-
17 proved labeling for the prescription drug.

18 “(i) PROHIBITION OF DISCRIMINATION.—

19 “(1) IN GENERAL.—It shall be unlawful for a
20 manufacturer of a prescription drug to discriminate
21 against, or cause any other person to discriminate
22 against, a pharmacist or wholesaler that purchases
23 or offers to purchase a prescription drug from the
24 manufacturer or from any person that distributes a

1 prescription drug manufactured by the drug manu-
2 facturer. *UNRECORDED*

3 “(2) DISCRIMINATION.—For the purposes of
4 paragraph (1), a manufacturer of a prescription
5 drug shall be considered to discriminate against a
6 pharmacist or wholesaler if the manufacturer enters
7 into a contract for sale of a prescription drug, places
8 a limit on supply, or employs any other measure,
9 that has the effect of— *etc.*

10 “(A) providing pharmacists or wholesalers
11 access to prescription drugs on terms or condi-
12 tions that are less favorable than the terms or
13 conditions provided to a foreign purchaser
14 (other than a charitable or humanitarian orga-
15 nization) of the prescription drug; or

16 “(B) restricting the access of pharmacists
17 or wholesalers to a prescription drug that is
18 permitted to be imported into the United States
19 under this section. *etc.*

20 “(j) CHARITABLE CONTRIBUTIONS.—Notwith-
21 standing any other provision of this section, section
22 801(d)(1) continues to apply to a prescription drug that
23 is donated or otherwise supplied at no charge by the man-
24 ufacturer of the drug to a charitable or humanitarian or-

1 ganization (including the United Nations and affiliates)
 2 or to a government of a foreign country.

3 “(k) WAIVER AUTHORITY FOR IMPORTATION BY IN-
 4 DIVIDUALS.—

5 “(1) DECLARATIONS.—Congress declares that
 6 in the enforcement against individuals of the prohi-
 7 bition of importation of prescription drugs and de-
 8 vices, the Secretary should—

9 “(A) focus enforcement on cases in which
 10 the importation by an individual poses a signifi-
 11 cant threat to public health; and

12 “(B) exercise discretion to permit individ-
 13 uals to make such importations in cir-
 14 cumstances in which—

15 “(i) the importation is clearly for per-
 16 sonal use; and

17 “(ii) the prescription drug or device
 18 imported does not appear to present an
 19 unreasonable risk to the individual.

20 “(2) WAIVER AUTHORITY.—

21 “(A) IN GENERAL.—The Secretary may
 22 *grant to individuals, by regulation or on a case-
 23 by-case basis, a waiver of the prohibition of im-
 24 portation of a prescription drug or device or
 25 class of prescription drugs or devices, under

such conditions as the Secretary determines to be appropriate.

“(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

“(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

“(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

“(B) is accompanied by a copy of a valid prescription;

“(C) is imported from Canada, from a seller registered with the Secretary;

“(D) is a prescription drug approved by the Secretary under chapter V;

1 “(E) is in the form of a final finished dos-
2 age that was manufactured in an establishment
3 registered under section 510; and

4 “(F) is imported under such other condi-
5 tions as the Secretary determines to be nec-
6 essary to ensure public safety.

7 “(I) STUDIES; REPORTS.—

8 “(1) BY THE INSTITUTE OF MEDICINE OF THE
9 NATIONAL ACADEMY OF SCIENCES.—

10 “(A) STUDY.—

11 “(i) IN GENERAL.—The Secretary
12 shall request that the Institute of Medicine
13 of the National Academy of Sciences con-
14 duct a study of—

15 “(I) importations of prescription
16 drugs made under the regulations
17 under subsection (b); and

18 “(II) information and docu-
19 mentation submitted under subsection
20 (d).

21 “(ii) REQUIREMENTS.—In conducting
22 the study, the Institute of Medicine shall—

23 “(I) evaluate the compliance of
24 importers with the regulations under
25 subsection (b);

“(II) compare the number of shipments under the regulations under subsection (b) during the study period that are determined to be counterfeit, misbranded, or adulterated, and compare that number with the number of shipments made during the study period within the United States that are determined to be counterfeit, misbranded, or adulterated; and

“(III) consult with the Secretary, the United States Trade Representative, and the Commissioner of Patents and Trademarks to evaluate the effect of importations under the regulations under subsection (b) on trade and patent rights under Federal law.

“(B) REPORT.—Not later than 2 years after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

“(2) BY THE COMPTROLLER GENERAL.—

1 “(A) STUDY.—The Comptroller General of
2 the United States shall conduct a study to de-
3 termine the effect of this section on the price of
4 prescription drugs sold to consumers at retail.

5 “(B) REPORT.—Not later than 18 months
6 after the effective date of the regulations under
7 subsection (b), the Comptroller General of the
8 United States shall submit to Congress a report
9 describing the findings of the study under sub-
10 paragraph (A).

11 “(m) CONSTRUCTION.—Nothing in this section limits
12 the authority of the Secretary relating to the importation
13 of prescription drugs, other than with respect to section
14 801(d)(1) as provided in this section.

15 “(n) EFFECTIVENESS OF SECTION.—

16 “(1) IN GENERAL.—If, after the date that is 1
17 year after the effective date of the regulations under
18 subsection (b) and before the date that is 18 months
19 after the effective date, the Secretary submits to
20 Congress a certification that, in the opinion of the
21 Secretary, based on substantial evidence obtained
22 after the effective date, the benefits of implementa-
23 tion of this section do not outweigh any detriment
24 of implementation of this section, this section shall
25 cease to be effective as of the date that is 30 days

1 after the date on which the Secretary submits the
2 certification.

3 “(2) PROCEDURE.—The Secretary shall not
4 submit a certification under paragraph (1) unless,
5 after a hearing on the record under sections 556 and
6 557 of title 5, United States Code, the Secretary—

7 “(A)(i) determines that it is more likely
8 than not that implementation of this section
9 would result in an increase in the risk to the
10 public health and safety;

11 “(ii) identifies specifically, in qualitative
12 and quantitative terms, the nature of the in-
13 creased risk;

14 “(iii) identifies specifically the causes of
15 the increased risk; and

16 “(iv)(I) considers whether any measures
17 can be taken to avoid, reduce, or mitigate the
18 increased risk; and

19 “(II) if the Secretary determines that any
20 measures described in subclause (I) would re-
21 quire additional statutory authority, submits to
22 Congress a report describing the legislation that
23 would be required;

24 “(B) identifies specifically, in qualitative
25 and quantitative terms, the benefits that would

1 result from implementation of this section (in-
 2 cluding the benefit of reductions in the cost of
 3 covered products to consumers in the United
 4 States, allowing consumers to procure needed
 5 medication that consumers might not otherwise
 6 be able to procure without foregoing other ne-
 7 cessities of life); and

8 “(C)(i) compares in specific terms the det-
 9 riment identified under subparagraph (A) with
 10 the benefits identified under subparagraph (B);
 11 and

12 “(ii) determines that the benefits do not
 13 outweigh the detriment.

14 “(o) AUTHORIZATION OF APPROPRIATIONS.—There
 15 are authorized to be appropriated such sums as are nec-
 16 essary to carry out this section.”.

17 (b) CONFORMING AMENDMENTS.—The Federal
 18 Food, Drug, and Cosmetic Act is amended—

19 (1) in section 301(aa) (21 U.S.C. 331(aa)), by
 20 striking “covered product in violation of section
 21 804” and inserting “prescription drug in violation of
 22 section 804”; and

23 (2) in section 303(a)(6) (21 U.S.C. 333(a)(6),
 24 by striking “covered product pursuant to section

804(a)” and inserting “prescription drug under section 804(b)”.

(c) CONDITIONS.—This section shall become effective only if the Secretary of Health and Human Services certifies to the Congress that the implementation of this section will—

(1) pose no additional risk to the public’s health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

TITLE IX—DRUG COMPETITION ACT OF 2003

SEC. 901. SHORT TITLE.

This title may be cited as the “Drug Competition Act of 2003”.

SEC. 902. FINDINGS.

Congress finds that—

(1) prescription drug prices are increasing at an alarming rate and are a major worry of many senior citizens and American families;

(2) there is a potential for companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs to enter into financial deals that could tend to restrain trade and greatly reduce competi-

tion and increase prescription drug expenditures for American citizens; and

(3) enhancing competition among these companies can significantly reduce prescription drug expenditures for Americans.

SEC. 903. PURPOSES.

The purposes of this title are—

(1) to provide timely notice to the Department of Justice and the Federal Trade Commission regarding agreements between companies with patent rights regarding brand name drugs and companies which could manufacture generic versions of such drugs; and

(2) by providing timely notice, to enhance the effectiveness and efficiency of the enforcement of the antitrust and competition laws of the United States.

SEC. 904. DEFINITIONS.

In this title:

(1) **ANDA.**—The term “ANDA” means an Abbreviated New Drug Application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(aa)).

(2) **ASSISTANT ATTORNEY GENERAL.**—The term “Assistant Attorney General” means the As-

1 sistant Attorney General in charge of the Antitrust
2 Division of the Department of Justice.

3 (3) BRAND NAME DRUG.—The term “brand
4 name drug” means a drug approved under section
5 505(c) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 355(c)).

7 (4) BRAND NAME DRUG COMPANY.—The term
8 “brand name drug company” means the party that
9 received Food and Drug Administration approval to
10 market a brand name drug pursuant to an NDA,
11 where that drug is the subject of an ANDA, or a
12 party owning or controlling enforcement of any pat-
13 ent listed in the Approved Drug Products With
14 Therapeutic Equivalence Evaluations of the Food
15 and Drug Administration for that drug, under sec-
16 tion 505(b) of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 355(b)).

18 (5) COMMISSION.—The term “Commission”
19 means the Federal Trade Commission.

20 (6) GENERIC DRUG.—The term “generic drug”
21 means a product that the Food and Drug Adminis-
22 tration has approved under section 505(j) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 355(j)).

1 (7) GENERIC DRUG APPLICANT.—The term
 2 “generic drug applicant” means a person who has
 3 filed or received approval for an ANDA under sec-
 4 tion 505(j) of the Federal Food, Drug, and Cosmetic
 5 Act (21 U.S.C. 355(j)).

6 (8) NDA.—The term “NDA” means a New
 7 Drug Application, as defined under section 505(b) et
 8 seq. of the Federal Food, Drug, and Cosmetic Act
 9 (21 U.S.C. 355(b) et seq.)

10 **SEC. 905. NOTIFICATION OF AGREEMENTS.**

11 (a) IN GENERAL.—

12 (1) REQUIREMENT.—A generic drug applicant
 13 that has submitted an ANDA containing a certifi-
 14 cation under section 505(j)(2)(vii)(IV) of the Fed-
 15 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 16 355(j)(2)(vii)(IV)) and a brand name drug company
 17 that enter into an agreement described in paragraph
 18 (2), prior to the generic drug that is the subject of
 19 the application entering the market, shall each file
 20 the agreement as required by subsection (b).

21 (2) DEFINITION.—An agreement described in
 22 this paragraph is an agreement regarding—

23 (A) the manufacture, marketing or sale of
 24 the brand name drug that is the subject of the
 25 generic drug applicant’s ANDA;

(B) the manufacture, marketing or sale of the generic drug that is the subject of the generic drug applicant's ANDA; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) FILING.—

(1) AGREEMENT.—The generic drug applicant and the brand name drug company entering into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that the generic drug applicant and the brand-name drug company shall not be required to file an agreement that solely concerns—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The generic drug applicant and the brand name drug company enter-

ing into an agreement described in subsection (a)(2) shall file with the Assistant Attorney General and the Commission the text of any other agreements not described in subsection (a)(2) between the generic drug applicant and the brand name drug company which are contingent upon, provide a contingent condition for, or are otherwise related to an agreement which must be filed under this title.

(3) DESCRIPTION.—In the event that any agreement required to be filed by paragraph (1) or (2) has not been reduced to text, both the generic drug applicant and the brand name drug company shall file written descriptions of the non-textual agreement or agreements that must be filed sufficient to reveal all of the terms of the agreement or agreements.

SEC. 906. FILING DEADLINES.

Any filing required under section 5 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

SEC. 907. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this title shall be exempt from disclosure under sec-

1 tion 552 of title 5, and no such information or documen-
2 tary material may be made public, except as may be rel-
3 evant to any administrative or judicial action or pro-
4 ceeding. Nothing in this section is intended to prevent dis-
5 closure to either body of Congress or to any duly author-
6 ized committee or subcommittee of the Congress.

7 **SEC. 908. ENFORCEMENT.**

8 (a) CIVIL PENALTY.—Any brand name drug com-
9 pany or generic drug applicant which fails to comply with
10 any provision of this title shall be liable for a civil penalty
11 of not more than \$11,000, for each day during which such
12 entity is in violation of this title. Such penalty may be
13 recovered in a civil action brought by the United States,
14 or brought by the Commission in accordance with the pro-
15 cedures established in section 16(a)(1) of the Federal
16 Trade Commission Act (15 U.S.C. 56(a)).

17 (b) COMPLIANCE AND EQUITABLE RELIEF.—If any
18 brand name drug company or generic drug applicant fails
19 to comply with any provision of this title, the United
20 States district court may order compliance, and may grant
21 such other equitable relief as the court in its discretion
22 determines necessary or appropriate, upon application of
23 the Assistant Attorney General or the Commission.

1 **SEC. 909. RULEMAKING.**

2 The Commission, with the concurrence of the Assist-
3 ant Attorney General and by rule in accordance with sec-
4 tion 553 of title 5 United States Code, consistent with
5 the purposes of this title—

6 (1) may define the terms used in this title;

7 (2) may exempt classes of persons or agree-
8 ments from the requirements of this title; and

9 (3) may prescribe such other rules as may be
10 necessary and appropriate to carry out the purposes
11 of this title.

12 **SEC. 910. SAVINGS CLAUSE.**

13 Any action taken by the Assistant Attorney General
14 or the Commission, or any failure of the Assistant Attor-
15 ney General or the Commission to take action, under this
16 title shall not bar any proceeding or any action with re-
17 spect to any agreement between a brand name drug com-
18 pany and a generic drug applicant at any time under any
19 other provision of law, nor shall any filing under this title
20 constitute or create a presumption of any violation of any
21 antitrust or competition laws.

22 **SEC. 911. EFFECTIVE DATE.**

23 This title shall—

24 (1) take effect 30 days after the date of enact-
25 ment of this title; and

- 1 (2) shall apply to agreements described in sec-
- 2 tion 905 that are entered into 30 days after the date
- 3 of enactment of this title.

Passed the Senate June 27 (legislative day, June 26), 2003.

Attest:

Secretary.

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108TH CONGRESS
1ST SESSION

S. 1

AN ACT

To amend title XVIII of the Social Security Act to provide for a voluntary prescription drug benefit under the medicare program and to strengthen and improve the medicare program, and for other purposes.

June 27 (legislative day, June 26), 2003

Ordered to be printed as passed